LABScan3D™ and xPONENT® 4.2 Quick Reference Guide

Software Version: Luminex® xPONENT 4.2

Revision • May 2015

This is only to be used as a guide—Verify this reference against the most current Luminex FLEXMAP 3D® Hardware User Manual IVD and Luminex xPONENT 4.2 Software User Manual IVD. If questions still exist, contact One Lambda Inc. Technical Support.

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Powering on the LABScan3D Unit

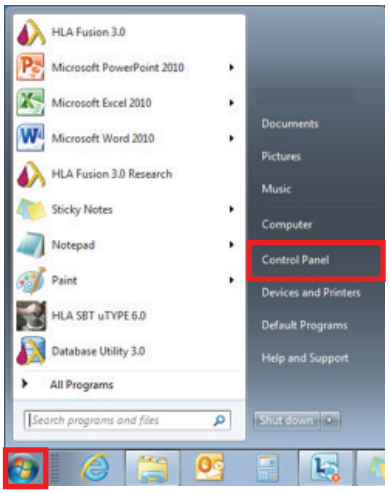
1. Turn on the computer and the LABScan3D unit (LABScan3D power switch is located on the bottom right hand side of the unit).

   Note: It takes approximately 30 minutes for the lasers to warm-up before being able to Calibrate or Verify the unit.

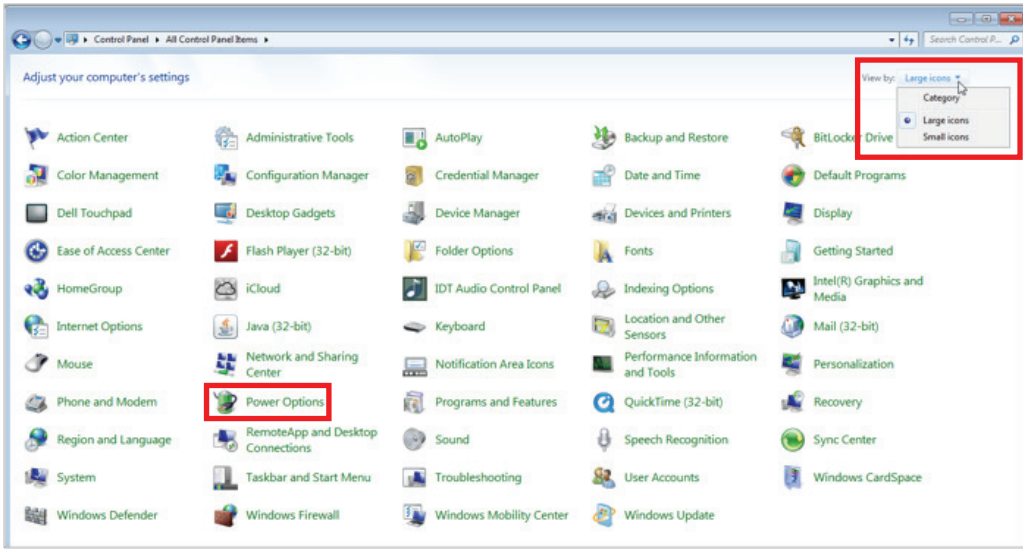
2. Double click the Luminex xPONENT icon: , the xPONENT 4.2 program will open.
3. Check the 20 liter Sheath Fluid and Waste Containers (if the sheath fluid needs replacement, be sure to prime the unit three times after replacement). *See Appendix H: Maintaining Fluids.*

User Computer Screen Saver and Power Saving Settings (Must be set before the 1st assay is run for EACH user login)

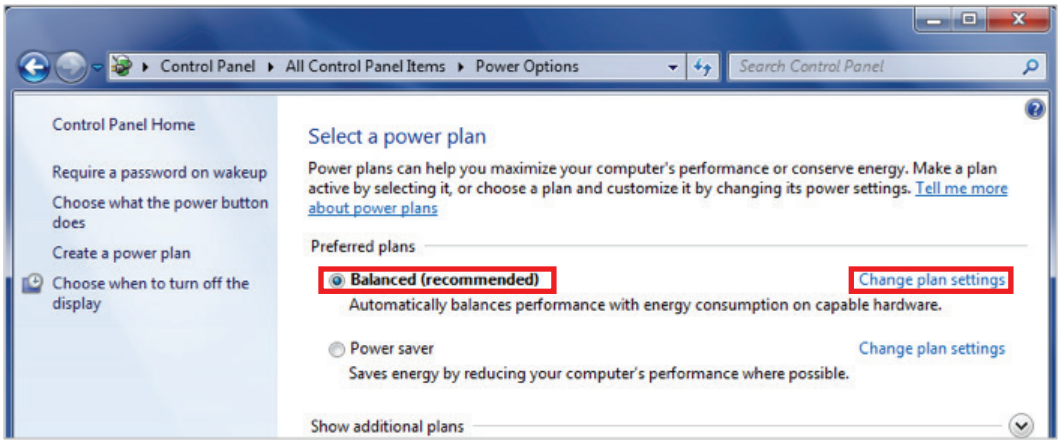
1. From the **Windows Start** menu, select **Control Panel**.

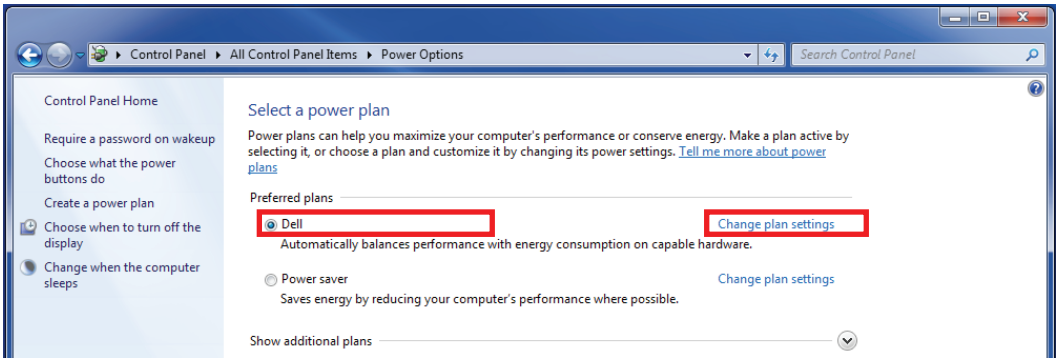


2. In the Control Panel window, if not already selected, select View by: Large icons, then click on the Power Options icon.

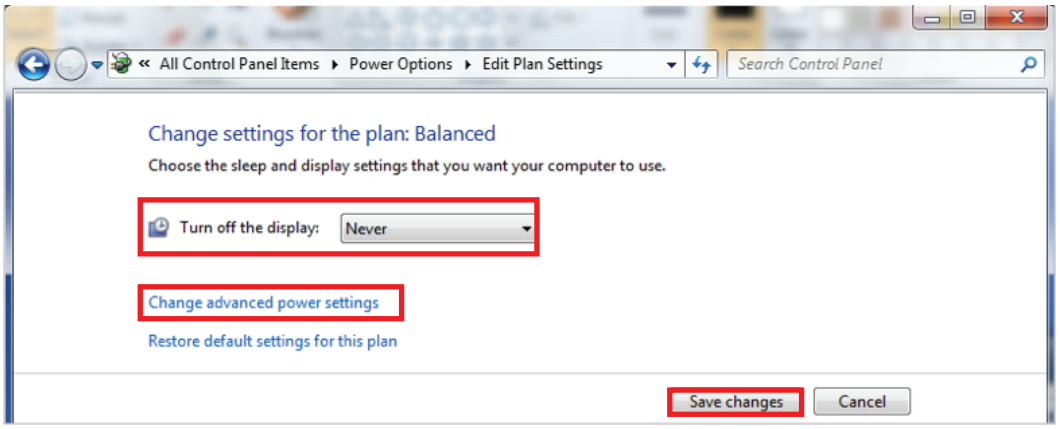


3. In the **Power options** window, under **Preferred plans**, select the **Balanced (recommended)** or **Dell** radio button and then click the **Change plan settings** link to the right.


Control Panel ▸ All Control Panel Items ▸ Power Options
Search Control Panel
Control Panel Home
Require a password on wakeup
Choose what the power button does
Create a power plan
Choose when to turn off the display
Select a power plan
Power plans can help you maximize your computer's performance or conserve energy. Make a plan active by selecting it, or choose a plan and customize it by changing its power settings. Tell me more about power plans
Preferred plans
Balanced (recommended)
Change plan settings
Automatically balances performance with energy consumption on capable hardware.
Power saver
Change plan settings
Saves energy by reducing your computer's performance where possible.
Show additional plans

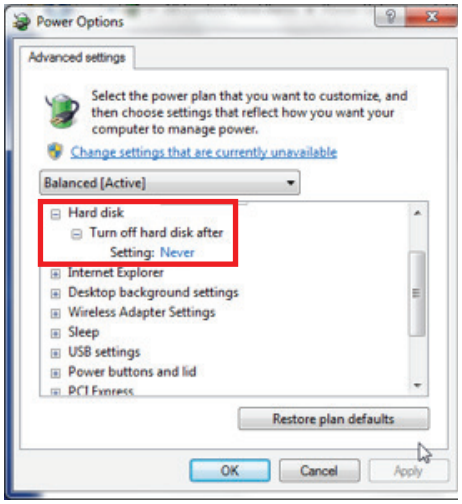

Control Panel ▸ All Control Panel Items ▸ Power Options
Search Control Panel
Control Panel Home
Require a password on wakeup
Choose what the power buttons do
Create a power plan
Choose when to turn off the display
Change when the computer sleeps
Select a power plan
Power plans can help you maximize your computer's performance or conserve energy. Make a plan active by selecting it, or choose a plan and customize it by changing its power settings. Tell me more about power plans
Preferred plans
Dell
Change plan settings
Automatically balances performance with energy consumption on capable hardware.
Power saver
Change plan settings
Saves energy by reducing your computer's performance where possible.
Show additional plans

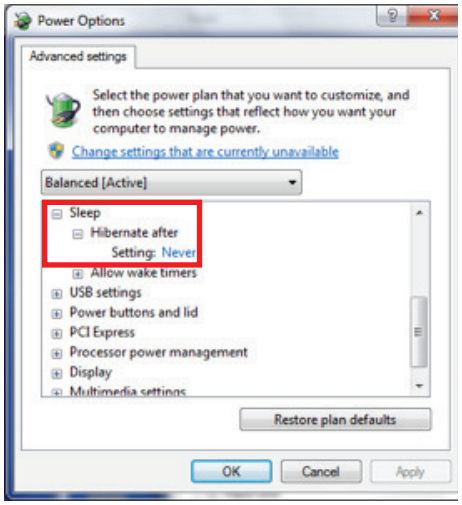
4. In the **Change settings for the plan: Balanced**, change the **Turn off the display**: pull down to **Never** (below), and click **Save changes**. (Clicking **Save Changes** will take the user back out to the **Power Options** page, re-select **Change plan settings** (same as above), then click on **Change advance power settings** (below).

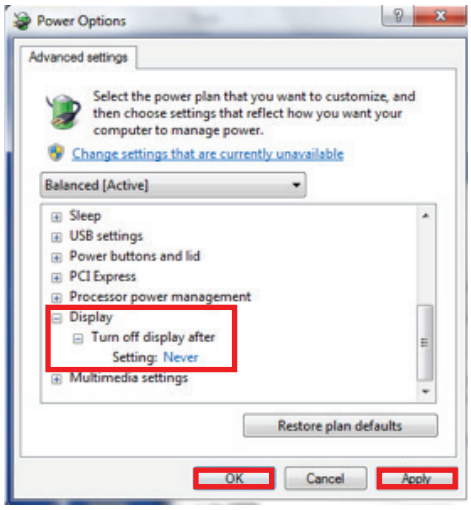

« All Control Panel Items ▸ Power Options ▸ Edit Plan Settings
Search Control Panel
Change settings for the plan: Balanced
Choose the sleep and display settings that you want your computer to use.
Turn off the display:
Never
Change advanced power settings
Restore default settings for this plan
Save changes
Cancel

5. On the **Advanced settings** window, make sure that the **Hard Disk> Turn off hard disk after** is set to **Never**, the **Sleep>Hibernate after** is set to **Never**, the **Display>Turn off display after** is set to **Never** and click **Apply, OK**, and **Exit**.

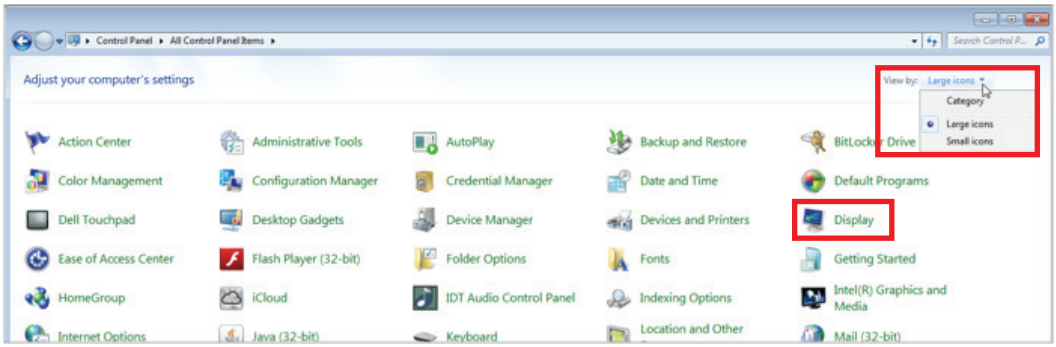
   Note: Manually type in "**Never**," or scroll down to **0 minutes**.



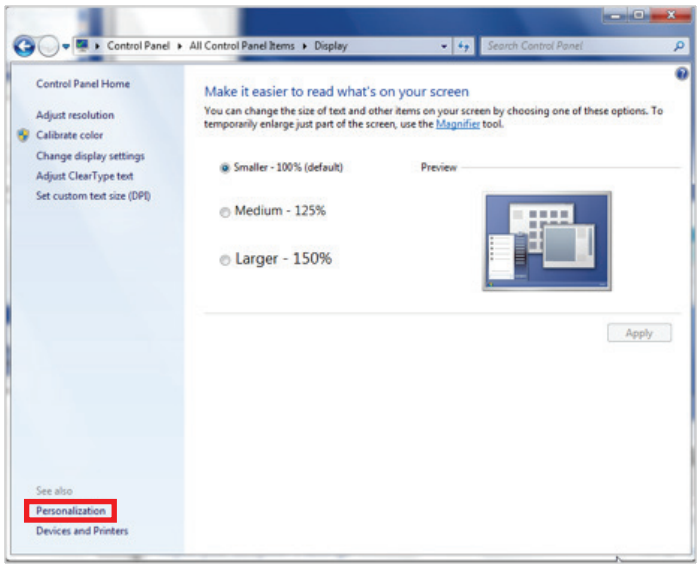




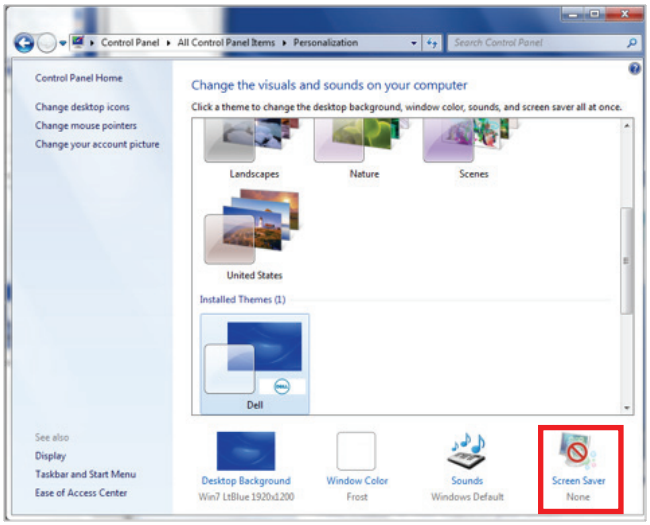
6. Again select the **Control Panel** from the **Windows Start** menu. Select **View by: Large icons**, then click on the **Displ**ay icon.

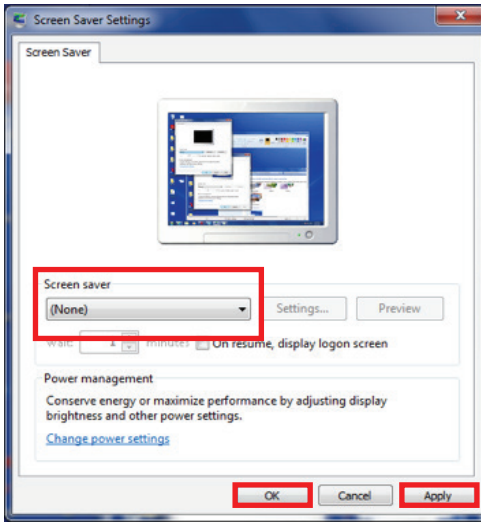


7. In the new window, click **Personalization** from the bottom left corner.


Control Panel ▸ All Control Panel Items ▸ Display
Control Panel Home
Adjust resolution
Calibrate color
Change display settings
Adjust ClearType text
Set custom text size (DPI)
Make it easier to read what's on your screen
You can change the size of text and other items on your screen by choosing one of these options. To temporarily enlarge just part of the screen, use the Magnifier tool.
Smaller - 100% (default)
Medium - 125%
Larger - 150%
Preview
Apply
See also
Personalization
Devices and Printers

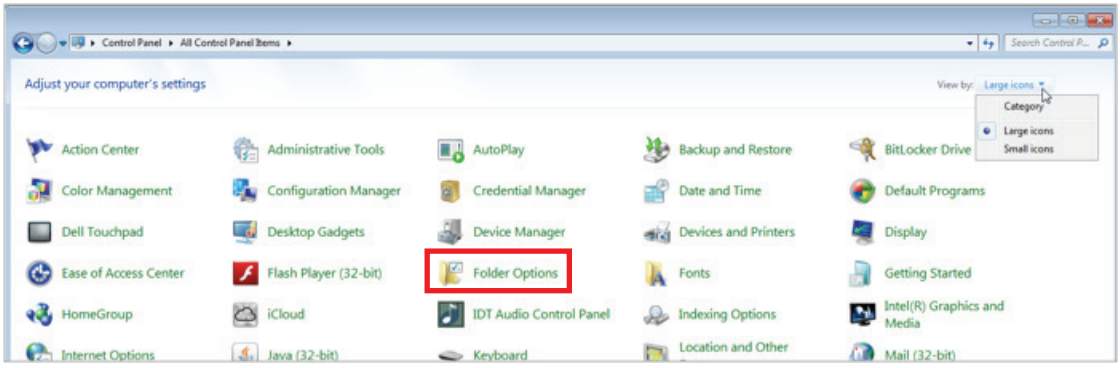
8. Select **Screen Saver** from the bottom right corner. In the **Screen Saver Settings** window, change to **(None)**, click **Apply, OK**, and **Exit.**



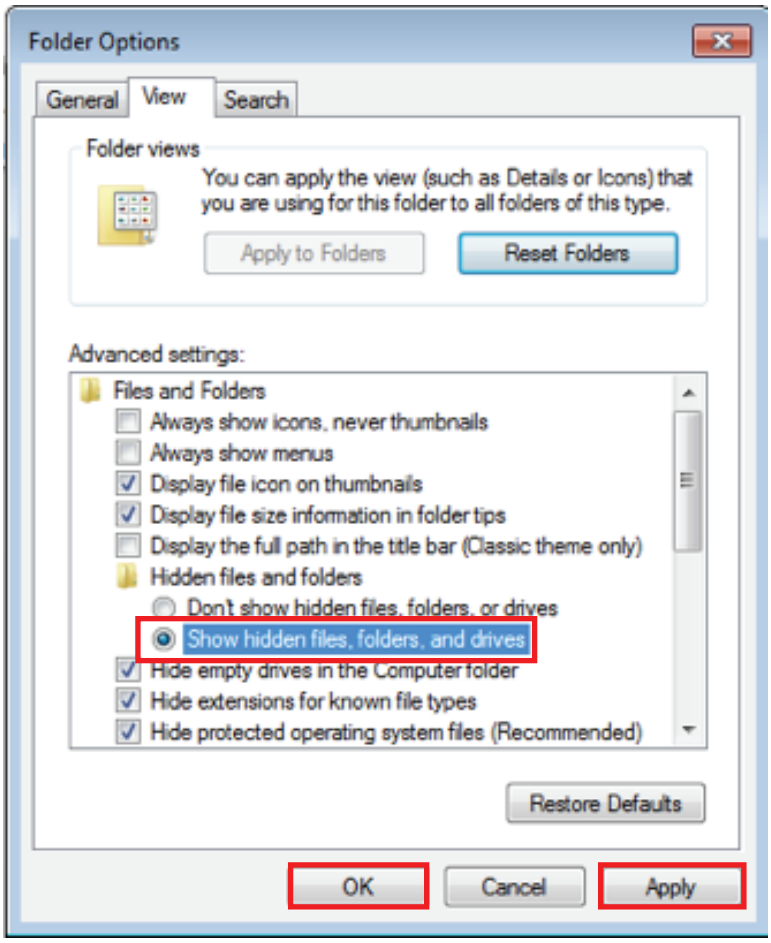


Un-hiding Hidden Files and Folders (Must be set for EACH user login)

1. Again select the **Control Panel** from the **Windows Start** menu. Select **View by: Large icons**, then click on the **Folder Options** icon.



2. In the **Folder Options** window, select the **View** tab, select the **Show hidden files, folders, and drives** radio button, click **Apply, OK,** and **Exit**.


Folder Options
General
View
Search
Folder views
You can apply the view (such as Details or Icons) that you are using for this folder to all folders of this type.
Apply to Folders
Reset Folders
Advanced settings:
Files and Folders
Always show icons, never thumbnails
Always show menus
Display file icon on thumbnails
Display file size information in folder tips
Display the full path in the title bar (Classic theme only)
Hidden files and folders
Don't show hidden files, folders, or drives
Show hidden files, folders, and drives
Hide empty drives in the Computer folder
Hide extensions for known file types
Hide protected operating system files (Recommended)
Restore Defaults
OK
Cancel
Apply

LABScan3D CSV Options Settings (Must be set before the 1st assay is run)

1. Before running any assays, check that the CSV options are set correctly Under the **Admin** tab, go to **CSV Options**.

   Note: Once these settings have been saved, **DO NOT** change them.
   Note: To update the License code for a full license, select **Licensing** under the **Admin** tab

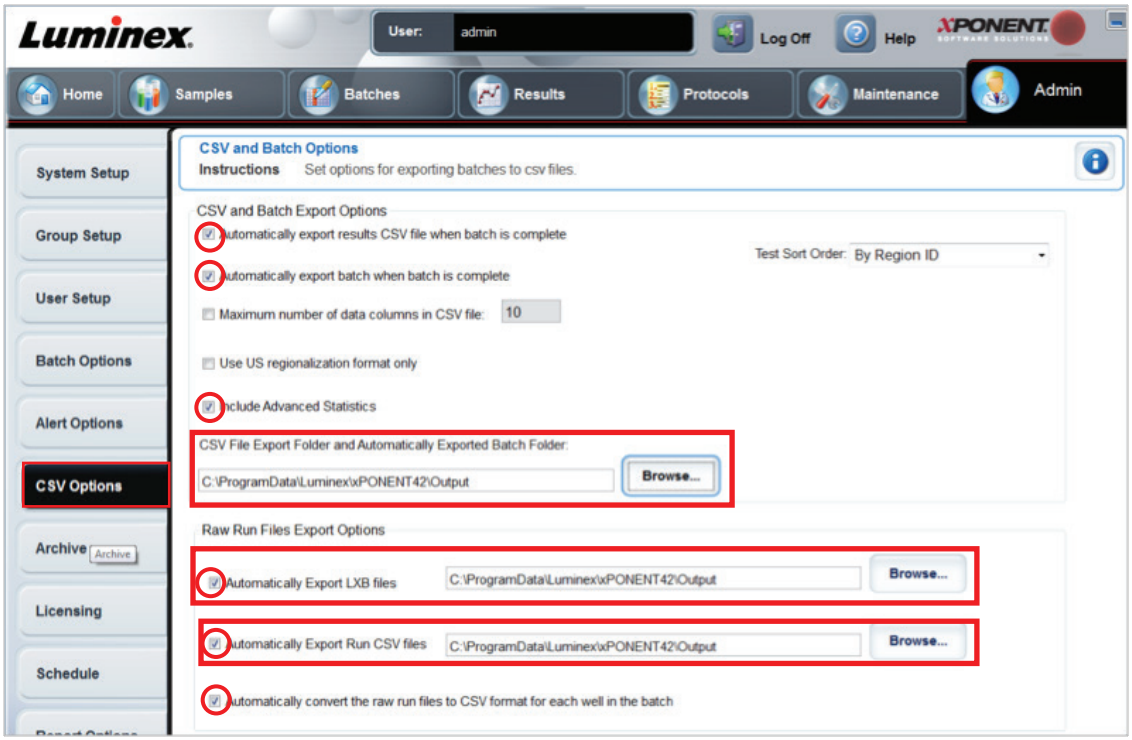
   a. **Verify that the following options are checked**: *(See Figure below)*
      i. **Automatically export results CSV file when batch is complete**
      ii. **Automatically export batch when batch is complete**
      iii. **Include Advanced Statistics**
      iv. **Automatically export LXB files**
      v. **Automatically export Run CSV files**
      vi. **Automatically convert the raw run files to CSV format for each well in the batch**

   b. Specify a folder for CSV Output files under **CSV Export Folder and Automatically Exported Batch Folder**.

   Note: This will change the location of the CSV Output files but will not change the location of the Run Files (.rcsv and .lxb files).

   c. Specify a folder for each **Raw Run Files Export Options**.
      i. **Automatically export LXB files**
      ii. **Automatically export Run CSV files**

   d. **Save** changes.



Adjusting the Probe Height for a LABType and LABScreen Plate (Must be set before the 1st assay is run)

Note: Each Protocol is created with a plate type built into the protocol based on the assay type. A plate type must be saved for both the LABType Assay and the LABScreen Assay Protocols.

Note: The probe height should be re-adjusted and saved for all plate types each time the probe is removed and replaced in the unit.

Note: The probe height should be adjusted before the first use of a new reading tray type/brand/lot.

Example: If the type of plate being used to run either the LABType or LABScreen Assay is changed, the **LABType Plate** and/or the **LABScreen Plate** must be re-adjusted and saved based on the probe height for the new plate. (Place the new plate in the unit, select the Plate from the **Plate Name** pull down menu, and click **Auto Adjust Height**.

The new height will be automatically updated to the selected plate).

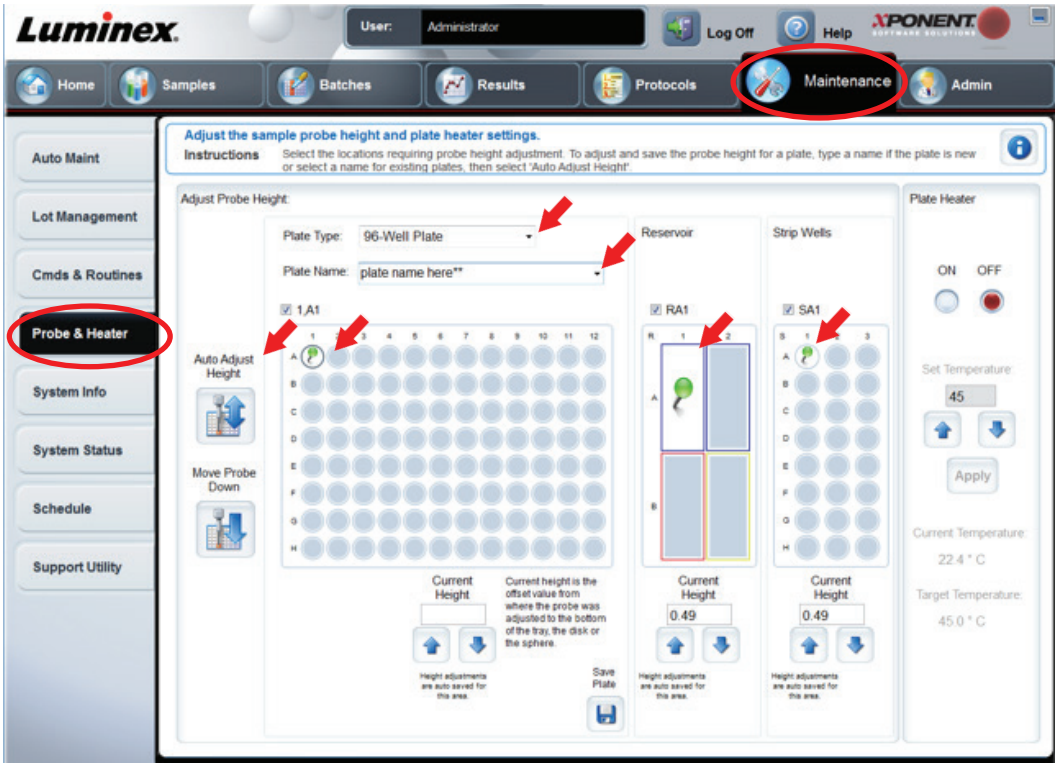
1. Refer to *Appendix A: Automatic Sample Probe Height Adjustment* for instructions on adjusting the probe height.
2. When naming the plate, name the plate (exactly): **LABType Plate**
3. Place the tray that will be used to read LABType assays onto the XY platform of the LABScan3D unit.
4. Click **Auto Adjust Height**

. The height will automatically save to the **Plate Name**.
5. Create a new plate, when naming the plate, name the plate (exactly): **LABScreen Plate**
6. Place the tray that will be used to read LABScreen assays onto the XY platform of the LABScan3D unit.

   Note: If using a filter bottom plate, place a large (5.08mm) alignment disk into the selected well; for other hard bottom plates, no disk or metal ball is required.

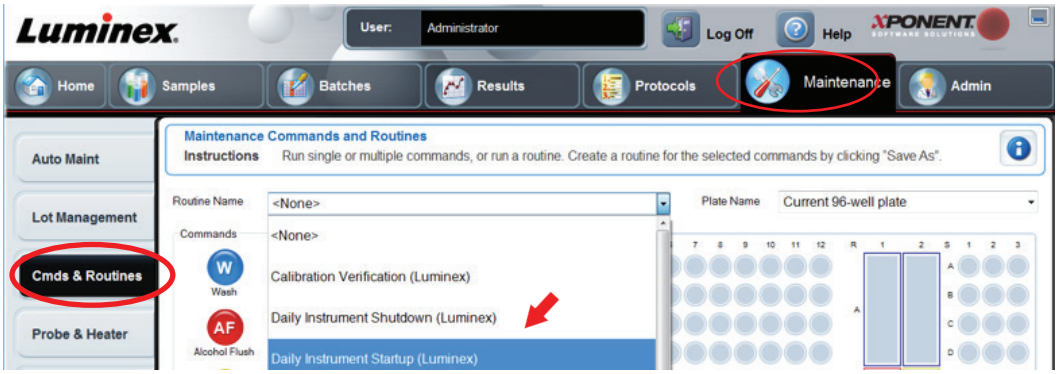
7. Click **Auto Adjust Height**

. The height will automatically save to the **Plate Name.**

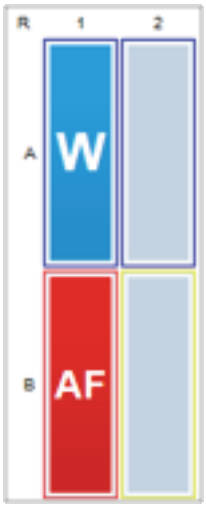


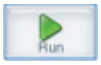
System Initialization

1. On the **Maintenance** tab, select the **Cmds & Routines** sub-tab from the left hand side, then on the pull down menu for **Routine Name**, select **Daily Instrument Startup (Luminex)**. *(See Figure below)*.



2. As indicated on the screen, fill the corresponding reservoirs with 70% alcohol solution and DI water.



3. Select the Run  button.

Other routines may be found under the **Routine Name** pull down menu.

Calibration/Verification

Note: In order to maintain the LABScan3D system, 6 month and 12 month PMs should be performed by Luminex, see *Appendix J: Schedule* to determine PM due dates.

Note: If Calibration or Performance Verification fails, see *Appendix D: Basic Instrument Troubleshooting*.

1. The LABScan3D unit must Calibrated **every 7 days** and the Performance Verification kit must be run every day the unit is used. If it has been more than seven days since the previous calibration, see Step 2; if the unit has been calibrated in the past seven days, see Step 3.

   Note: The Calibration and Performance Verification status of the unit may be checked on the **Maintenance** tab by selecting **System Info** sub-tab on the left-hand side.

Calibration/Verification

2. On the **Maintenance tab**, select the **Auto Maint** sub-tab, then select the bubble for **Calibration/Verificatio**n.

   Note: Calibration must be followed by **Performance Verification**.

   a. Select the correct lots of the **Calibration Kit** and **Performance Verification Kit** in each of the corresponding pull down menus. *(See Figure below)*

Note: Verify that the lot numbers of the calibration and performance verification reagent bottles in use match up to the corresponding kit lot numbers. Lot information is located under **Maintenance > Lot Management**. If a calibration or performance verification kit needs to be imported to the LABScan3D software, see *Appendix B: Downloading Calibration Kit or Performance Verification Kit Information for Import into xPONENT Software.*

Note: For information regarding the purpose of each Calibration and Verification reagent, see *Appendix C: Calibration and Verification Bead Information*

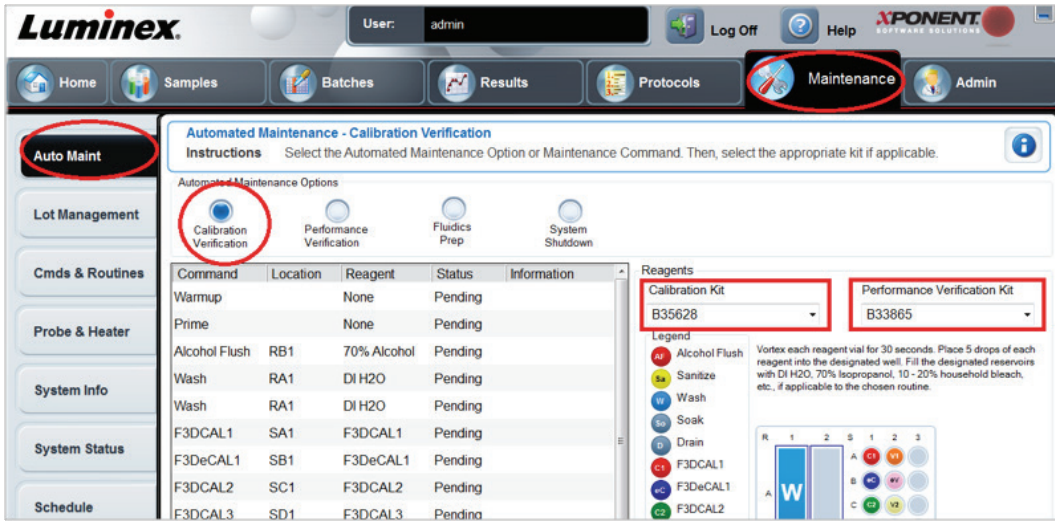
b. Vortex each calibration and performance verification reagent bottle for at least 30 seconds.

c. **Eject** the plate and insert two empty plastic strip wells into lanes 1 and 2 in the strip well holder.

d. According to the image in the display window, add **5 drops each** of calibration and verification reagent beads to the designated wells, inverting the vials completely when adding the drops.

e. Before retracting the plate, be sure there is sufficient DI water in the water reservoir.

f. **Retract** plate and select **Run** .



Performance Verification Only

1. On the **Maintenance** tab, select the **Auto Maint** sub-tab, then select the bubble for **Performance Verification**.

   a. Select the correct lots of the **Performance Verification Kit** in the **Performance Verification Kit** pull down menu. *(See Figure below)*

   Note: Verify that the lot numbers of the performance verification bottles match up to the corresponding kit lot numbers. Lot information is located under **Maintenance > Lot Management**. If a performance verification kit needs to be imported to the LABScan3D software, see *Appendix B: Downloading Calibration Kit or Performance Verification Kit Information for Import into xPONENT Software.*

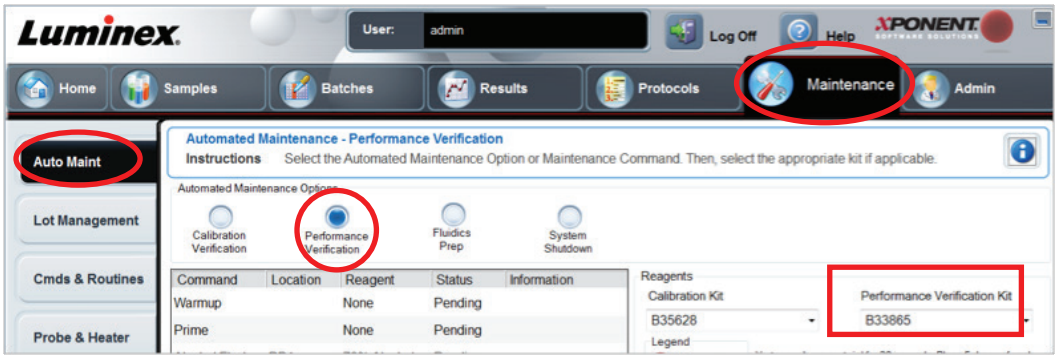
   b. Vortex each performance verification reagent bottle for at least 30 seconds.

   c. **Eject** the plate and insert one empty plastic strip well into lane two in the strip well holder.

   d. According to the image in the display window, add **5 drops each** of verification reagent beads to the designated wells, inverting the vials completely when adding the drops.

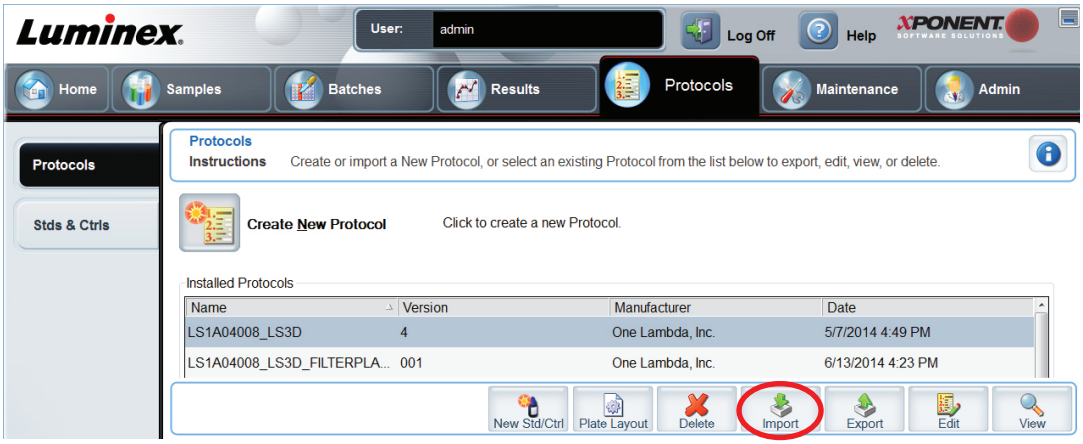
   e. Before retracting the plate, be sure there is sufficient DI water in the water reservoir.

   f. **Retract** plate and select **Run** .



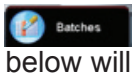
Import Protocol

1. In the LABScan3D window, select the **Protocols** tab.
2. Click the **Import** button at the bottom. *(See Figure below)*



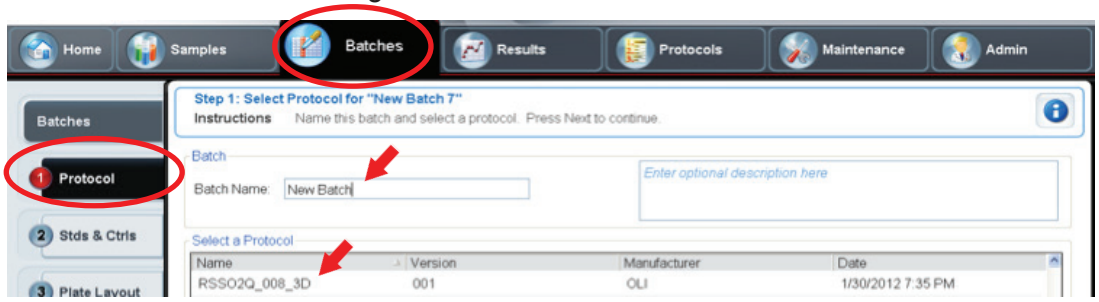
3. Browse to the location of the saved protocol information.
4. A prompt will open saying that the protocol was successfully imported.
5. The imported protocol should be displayed under **Installed Protocols** on the **Protocols** tab.

Create a Batch

1. Select the **Batches** tab  at the top of the display window; the following options shown below will be displayed in the window.

Create a New Batch from an existing Protocol
Click to create a new batch from an existing protocol.
Create a New Batch from a new Protocol
Click to create a new batch without using a protocol.
Create a New Multi-Batch
Click to create a new multi-batch from pending batches.

2. Click **Create a New Batch from an existing Protocol** .
3. Enter a **Batch Name** for the samples to be run. *(See Figure below)*
4. Select the protocol to be used from the **Select a Protocol** list.
5. Click **Next** in the bottom right of screen.



6. Select all the wells to be read by clicking and dragging over them with the cursor.

Note: If creating batches for use in a multi-batch, DO NOT move the starting well position.

7. Then select to assign the wells as **Unknown**. *(See Figure below)*

8. Next, either click **Import List** to import a Sample ID Import list to the batch, or edit the Sample ID of each well by double clicking in the **ID** field next to the corresponding well position, and give each "ID" a sample name.

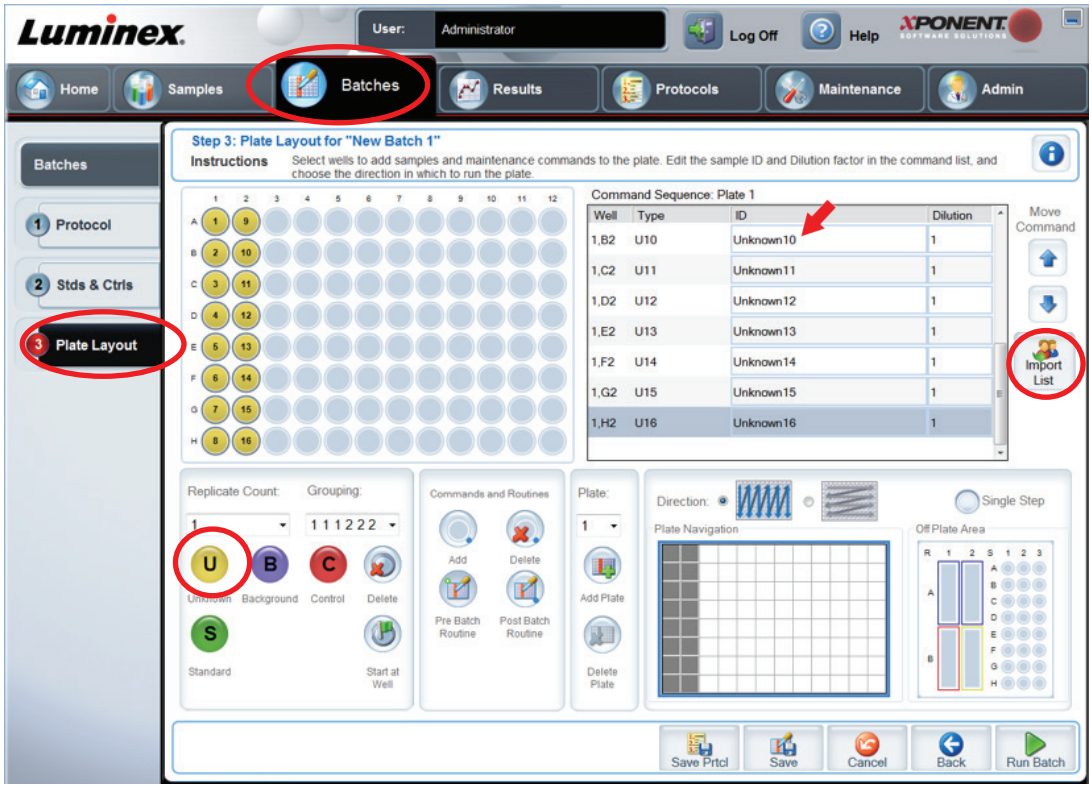
   Note: In order to edit Patient IDs/Sample IDs after a batch has completed, see *Appendix G: Edit Patient ID/Sample ID*

Notes regarding the Sample ID Import List

Note: A Sample ID Import list must be a .txt file created in notepad (or equivalent) with one Sample ID per line.

Note: The 2 line heading that was required in Luminex IS2.3 Sample ID Import list is no longer required, however, if present, the heading does not affect the Sample IDs imported to the batch (LX100IS Patient List, [Accession#, Dilution Factor]).

Note: The number of samples in the Sample ID Import list must match the number of **Unknown**s selected. If the Sample ID Import list is longer than the number of **Unknown**s selected, only the Sample IDs equaling the number of **Unknown**s on the plate will be imported. If the Sample ID Import list is shorter than the number of **Unknown**s selected, the excess **Unknown**s will still be labeled as "UnknownX."



9. If the batch is going to be run immediately, go to “Run a Batch Step 1,” (below). If the batch is going to be run later, click **Save** and the batch will appear on the lower portion of the **Batches** tab until use (as a pending batch); when it is time to run a saved batch, simply click on the pending batch from the Batches tab, and go to “Run a Batch Step 1.”

Run a Batch

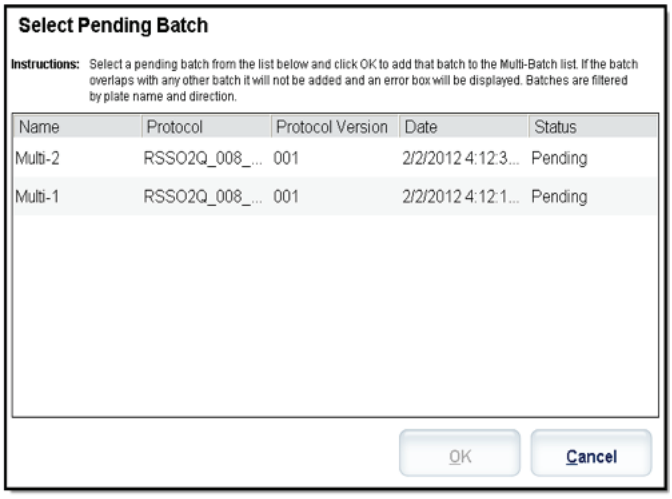
Note: Batch output data files are very large, in order to maintain software speed, regular archives should be performed, See Appendix I: Archive

1. Click **Eject** at the bottom of the screen and load the plate to be read.
   Note: Check the plate orientation and verify that well A1 is at the top left hand corner of the plate holder.
2. Click **Retract** .
3. When ready to begin playing the batch, click **Run Batch** at the bottom right hand corner of the screen.
4. After the batch has completed running, if any samples need to be re-run, see *Appendix E: Re-reading Individual Sample Wells*, or if a batch needs to be replayed, see *Appendix F: Replaying a Batch*.
5. Once completed, click **Eject** and remove the plate.
6. Click **Retract** .

Create a Multi-Batch:

Note: In order to create a New Multi-Batch, pending batches are needed. See **Create a Batch** above steps 1-9, in step 9 click **Save** and a pending batch will appear in the lower portion of the **Batches** tab.

1. On the **Batches** tab, create a batch for each assay to be run on the Multi-Batch and **Save**.
2. Click **Create a New Multi-Batch** .
3. A Prompt will open *(see Figure below)*, select the Pending Batch as it should appear on the reading tray, then select the **OK** button.



Note: Position of placed batches may be moved using the **Move** button.

4. Select the start position of next batch and click the **Add** button. Select the next batch to be read and repeat until all batches are added. *(See Figure below)*
5. Click **Eject** at the bottom of the screen and load the plate to be read.

   Note: Check the plate orientation and verify that well A1 is at the top left hand corner of the plate holder.

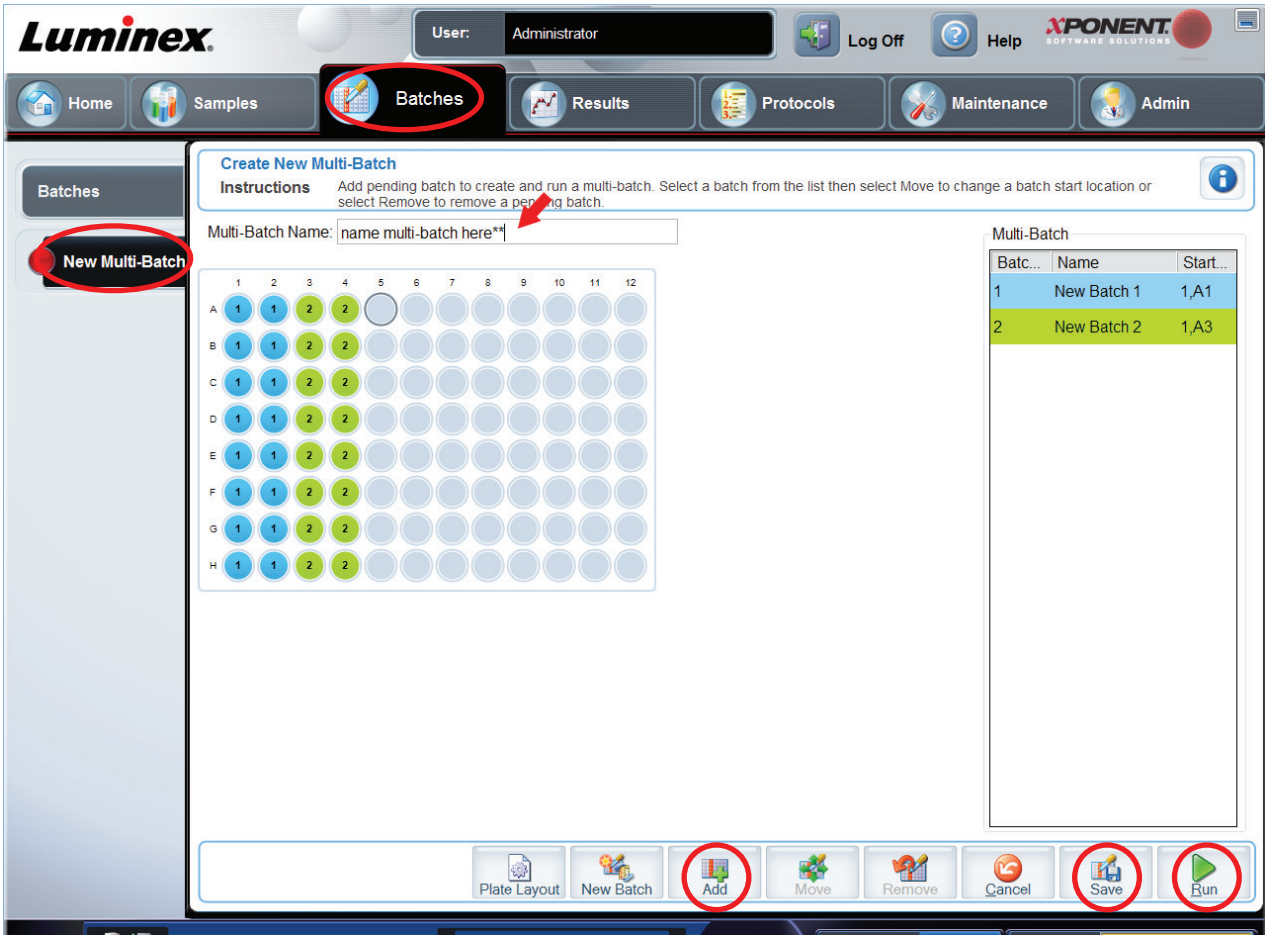
6. Click **Retract** .
7. When ready to begin playing the batch, click **Run** at the bottom right hand corner of the screen.

   Note: Multi-Batches may be saved and run at a later time. In order to save the Multi-Batch, name the Multi-Batch under **Multi-Batch Name**: and click the **Save** button . The Multi-Batch will appear on the **Batches** tab under **Pending Batches**.

8. After the tray has completed running, if any samples need to be re-run, see *Appendix E: Re-reading Individual Sample Wells*, or if a batch needs to be replayed, see *Appendix F: Replaying a Batch*.

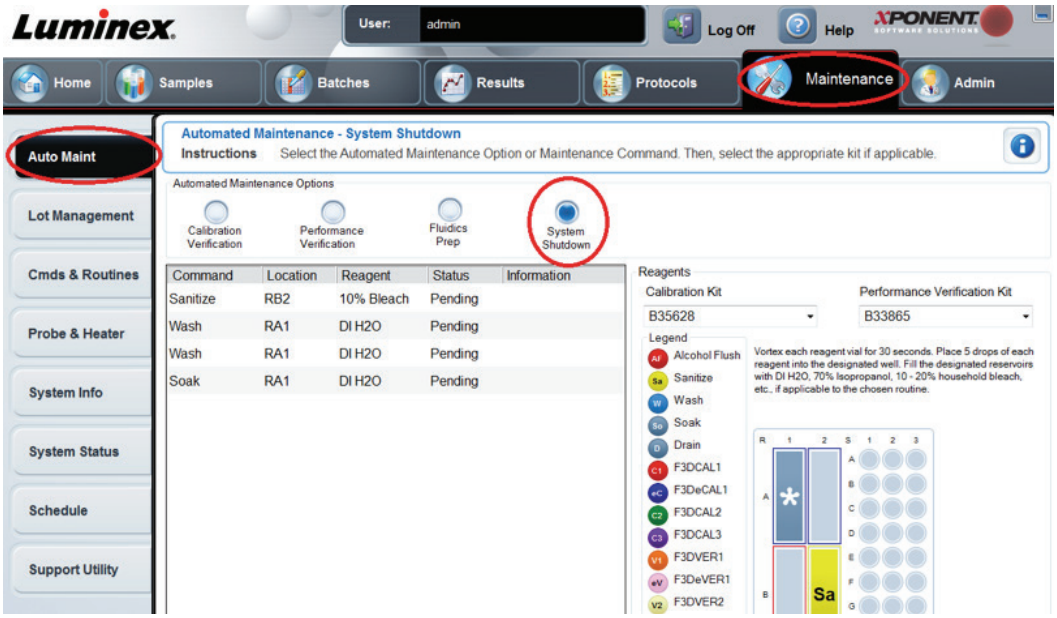
9. Once completed, click **Eject** and remove the plate.

10. Click **Retract** .



LABScan3D Unit Shutdown

1. On the **Maintenance** tab, select the **Auto Maint** sub-tab.
2. Select the **System Shutdown** bubble.
3. **Eject** the tray and fill the correct reservoirs with 10% bleach solution and DI water.



4. **Retract** tray and select the **Run** button at the bottom right corner of the screen.
5. Once the **System Shutdow**n is complete, exit the software and turn off the LABScan3D unit by flipping the switch located on the bottom right hand side of the unit.

Locate Data

1. Once a batch is completed, locate the CSV output file (and .rcsv Run Files –for HD or XR kits), and transfer them to a known location for data analysis. a. CSV output Files and Run files are located at the location specified on **Admin> CSV Options** (See **LABScan 3D CSV Options Settings**, page 9).

Data Analysis

1. Refer to the *HLA Fusion User Manual*.

Appendices:

Appendix A: Automatic Sample Probe Height Adjustment

Note: Each Protocol is created with a plate type built into the protocol based on the assay type. A plate type must be saved for both the LABType Assay and the LABScreen Assay Protocols.

Note: The probe height should be re-adjusted and saved for all plate types each time the probe is removed and replaced in the unit.

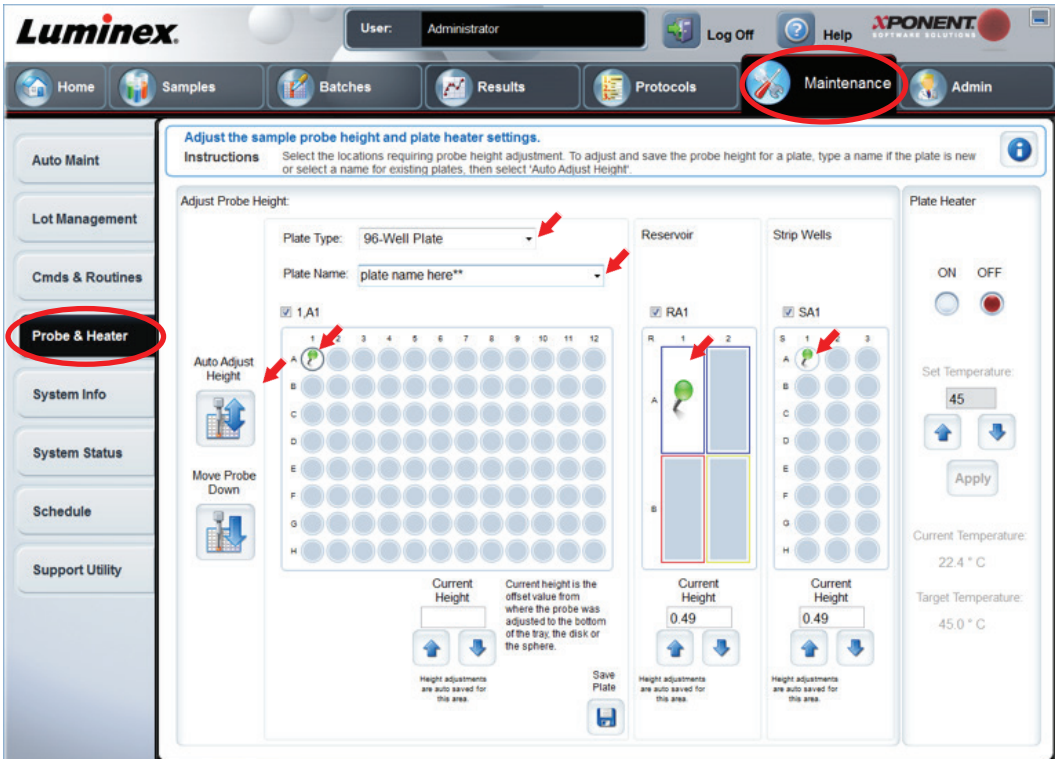
Note: The probe height should be adjusted before the first use of a new reading tray type/brand/lot.

Example: If the type of plate being used to run either the LABType or LABScreen Assay is changed, the **LABType Plate** and/or the **LABScreen Plate** must be re-adjusted and saved based on the probe height for the new plate. (Place the new plate in the unit, select the Plate from the **Plate Name** pull down menu, and click **Auto Adjust Height**

. The new height will be automatically updated to the selected plate)

1. On the **Maintenance** tab, select the **Probe & Heater** sub-tab.
2. Select the **Plate Type** from the pull down menu (either 96-Well Plate or 384-Well Plate) and give the selected plate a **Plate Name**.
   Note: The LABScan3D unit can store the probe height settings for different types of trays or different lots of trays as long as the tray is saved.
3. Select the locations on the plate that the probe height will automatically adjust to. The height must be adjusted to one plate well, one reservoir well, and one strip well location. (See Figure below, wells A1, RA1, and SA1 are selected).

   Note: the selected well of plate, strip well, and reservoir must NOT contain any liquid.



4. If using a filter bottom plate, place a large (5.08mm) alignment disk into the selected well; for other hard bottom plates, no disk or metal ball is required

   Note: Verify that the plate is not warped. Warped plates may lead to incorrect probe height adjustment.

5. Click **Eject** at the bottom of the screen.
6. Place a new, empty plate onto the plate holder with well A1 in the top left hand corner.
7. Insert a new, empty plastic strip well into the selected lane and place the reservoir into the reservoir holder.

   Note: Verify that all selected wells and reservoirs are **EMPTY** and **DRY**.

8. Click **Retract** .
9. Click **Auto Adjust Height** . The height will automatically save to the **Plate Name**.

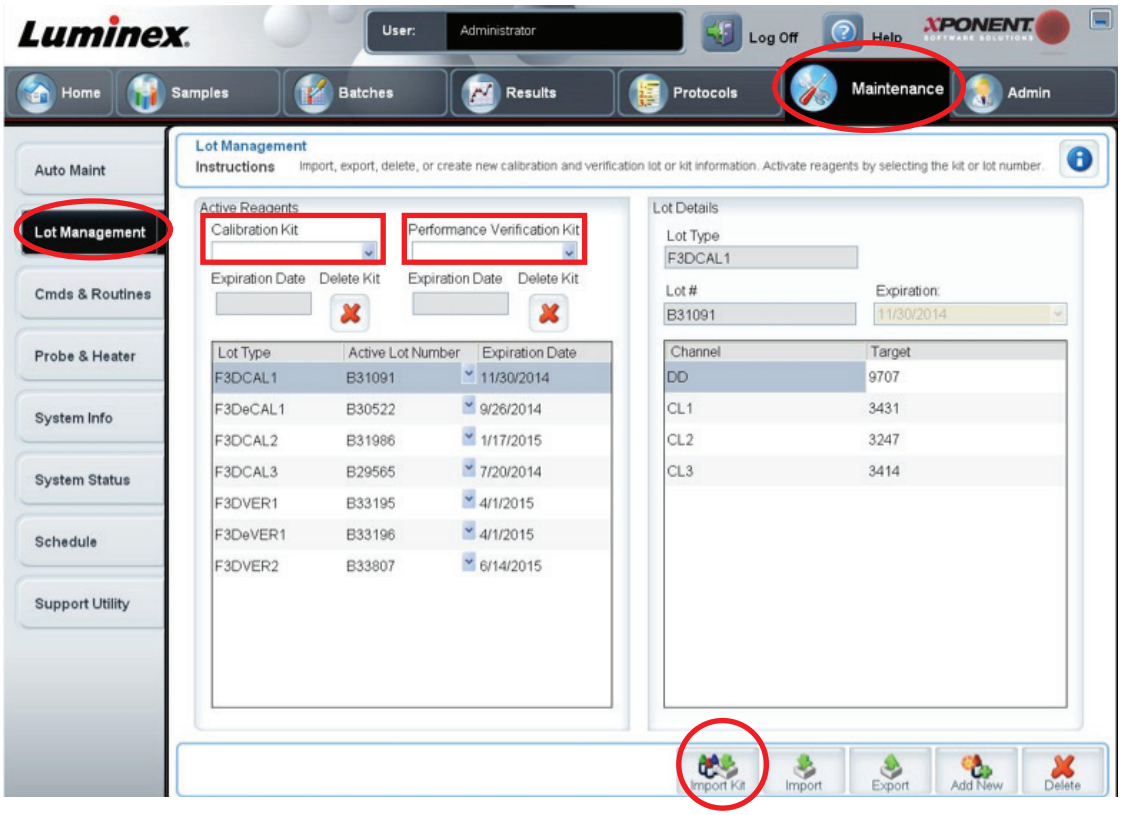
Appendix B: Downloading Calibration Kit or Performance Verification Kit Information for Import into xPONENT Software

1. Insert the Calibration Kit or Performance Verification Kit CD into the CD drive on the computer.

   Note: If the Calibration Kit or Performance Verification Kit CDs are misplaced, the same information is also available on the Luminex website: http://www.luminexcorp.com/.

   a. At the top go to the **Resources** tab and on the pull down menu, under **Target Values** click on **FLEXMAP 3D®**.
   b. Locate and "save as" the corresponding calibration or performance verification kit to a known location on the computer.
2. On the xPONENT software, select the **Maintenance** tab and click on the **Lot Management** sub-tab.
3. On the bottom right hand corner of the display window, click **Import Kit**

.
4. A browser window will appear; browse to the location of the CD drive on the computer (or the known location of the information downloaded from the Luminex website).
5. Open the .lxl file for the corresponding kit; if the kit imports properly, a prompt will appear verifying the kits installation.
6. Once the kit is imported, select the kit from the pull-down menu (Calibration Kit or Performance Verification Kit) to activate the lot.



Appendix C: Calibration and Verification Bead Information

Calibrators

1. **F3DCAL1-05:** Classification Calibrator for non-magnetic beads (calibrates DD, CL1, CL2, CL3)
2. **F3DeCAL1-05:** Classification Calibrator for magnetic beads (calibrates DD, CL1, CL2, CL3)
3. **F3DCAL2-05:** Reporter Calibrator (calibrates RP1 standard and enhanced range – all beads)
4. **F3DCAL3-05**: Extended Dynamic Range Calibrator (calibrates RP1 extended range - all beads)

Verifiers

1. **F3DVER1-05:** Verification Calibrator for non-magnetic beads (verifies DD, CL1, CL2, CL3)
   a. Comprised of 11 known regions of the bead map (6, 22, 71, 81, 96, 102, 153, 352, 374, 378, 500)
2. **F3DeVER1-05:** Verification Calibrator for magnetic beads (verifies DD, CL1, CL2, CL3)
   a. Comprised of 11 known regions of the bead map (6, 22, 71, 81, 96, 102, 153, 352, 374, 378, 500)
3. **F3DVER2-05:** Reporter Verifier (verifies RP1 standard PMT, high PMT, and extended range)
   a. Do not correlate to known regions on the bead map

Fluidics

1. **FLUID1-05:** Verifies targeting/quantity of one known region
2. **FLUID2-05:** Verifies targeting/quantity of second known region; Verifies Bead carryover in region of Fluidics 1

Appendix D: Basic Instrument Troubleshooting

Note: If needed, see the back cover for One Lambda Inc. Technical Support Contact Information and Luminex Technical Support Contact Information.

Note: if needed, see *Appendix K: Support Utility* for instructions on creating a **Support Utility Output File**.

1. **Sample Probe Clog**
   a. Sonicate the probe for 3-5 minutes in a 15mL falcon tube – the narrow end of the probe should be at the bottom of the falcon tube and slightly immersed in ~5mm of DI water (within the tube).
   b. Flush the probe with DI water from the **narrow** end so the DI water flows out of the larger end.
   c. Replace the sample probe and adjust the probe height (*see Appendix A: Automatic Sample Probe Height Adjustment* above).
   d. Under **Maintenance** tab, click on **Cmds & Routines** on the left hand side.
   e. In the **Routine Name** drop down menu, select **Remove Clog (Luminex)** procedure.
   f. A series of commands will populate under **Commands Sequence**:
   Backflush (2X), Wash, Backflush, Drain (3X), Alcohol Flush (2X), and Wash (3X).
   g. Click **Eject** and fill corresponding reservoirs with DI water and 70% alcohol solution according to reservoir illustration.
   h. Click **Retract** .
   i. Click **Run** .

2. **Calibration or Verification Failure**
   a. Verify that the probe height is adjusted for the plate being used.
   b. Verify correct lot numbers for both Calibration and Performance Verification beads.
   c. Verify bottles were properly mixed prior to use; at least 30 seconds on the vortex.
   d. Verify correct wells have been selected on the XY Platform.
   e. Verify that at least 5 drops of the calibration and performance verification reagent beads were used.
   f. Verify that there are bubbles in the wells, signaling the uptake of the beads (if not, the sample arm may not have moved; check the system pressurization. See *Appendix D: Basic Instrument Troubleshooting*, *Step 6: System Pressurization*.
   g. If the above steps have been completed, verify that there were at least 250 events/sec or more during Calibration/Verification and the pressure is between 6-9 psi.
   h. If the event/sec rate is too low, there may be a clog in the system. *See Appendix D: Basic Instrument Troubleshooting Step 1: Sample Probe Clog.*
   i. Rerun the Calibration/Verification or the Performance Verification on the system.
   j. If the Calibration/Verification or the Performance Verification fails, call Luminex Technical Support.
   k. Luminex Technical Support may request the “Stringent Clean” Routine be run on the unit See Below *Appendix D: Basic Instrument Troubleshooting, Step 3: “Stringent Clean” Routine.*

3. **“Stringent Clean” Routine**

The unit may have an internal clog that the **Remove Clog** routine could not resolve.

a. Sonicate the probe for 5-6 minutes in a 15mL falcon tube – the narrow end of the probe should be at the bottom of the falcon tube and slightly immersed in ~5mm of DI water (within the tube).

b. Flush the probe with DI water from the **narrow** end so the DI water flows out of the larger end.

c. Replace the sample probe and adjust the probe height (see *Appendix A: Automatic Sample Probe Height Adjustment* above).

d. Select the **Maintenance Tab** > **Cmds & Routines**.

e. Create the following routine:

i. **Prime** three times .

ii. Select RA2 reservoir (top right reservoir) add the **Sanitize** command twice .

iii. Select RB2 reservoir (bottom right reservoir) add the **Sanitize** command twice .

iv. **Backflush** .

v. **Drain** into SF1 (stripwell) .

vi. **Backflush**.

vii. **Drain** into SG1 (stripwell).

viii. **Backflush**.

ix. **Drain** into SH1.

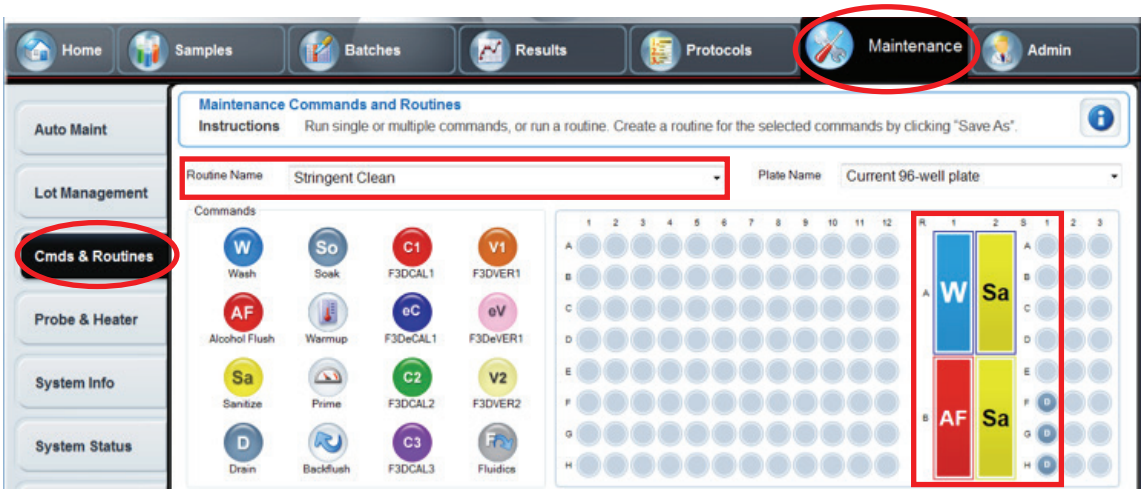
x. Select RB1 reservoir (bottom left reservoir) add the **Alcohol Flush** command twice.

xi. Select RA1 reservoir (top right reservoir) add the **Wash** command three times .

xii. Click the **Save As** button at the bottom, name the Routine “Stringent Clean” (it will now be available in the **Routine Name** pull-down menu).

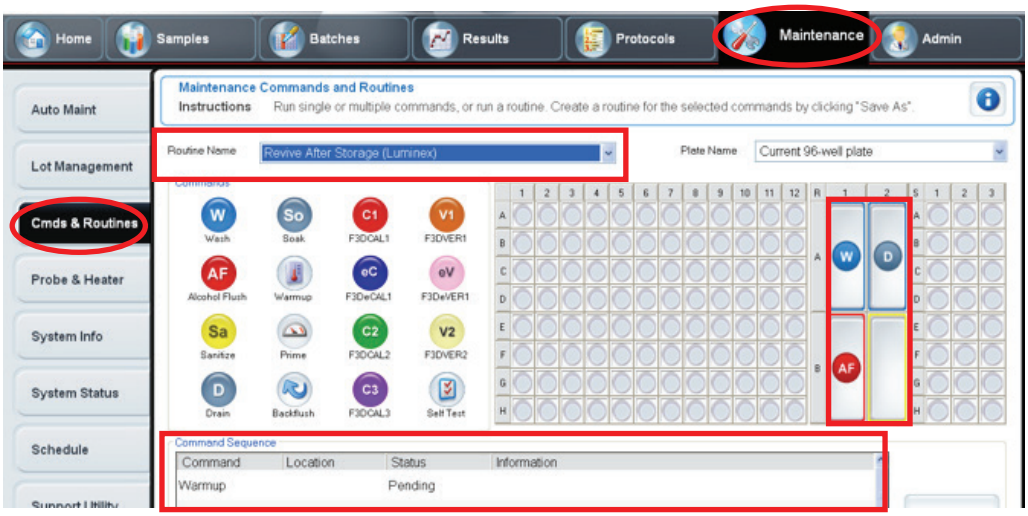
f. Fill Reservoir RA1 with DI water, RA2 with 0.1N NaOH, RB1 with 70% Alcohol, and RB2 with 10-20% Bleach. Also place an empty stripwell into S1.

g. Click **Run** .



4. **Infrequent Use of Unit**
   If a unit has not been used for over a week, a **Revive After Storage (Luminex)** routine should be run on the unit before use.
   a. Select the **Maintenance Tab > Cmds & Routines**.
   b. In the **Routine Name** pull-down, select **Revive After Storage (Luminex)**, notice that **Command Sequence** populates with the routine.
   c. Fill the appropriate reservoirs with required buffers.
   d. Click **Run**

.



5. **Command state is "Disconnected."**
   a. Verify that the outlets have power.
   b. Power off the computer and LABScan3D Unit.
   c. Check the power cords and communication cable connections.
   d. Power on the computer and LABScan3D Unit.
   e. Verify that the Firmware is up to date – check by selecting the **Maintenance** tab and then select **System Info** on the left.

6. **System Pressurization**
   Normal air and sheath pressure readings are 6-9 psi while the compressor is running. If the system is not pressurizing properly, verify the following.
   a.Check inside the instruments for leaking fluid. If large leaks are present, contact Luminex Technical Support.
   b. Make sure the tubing from the sheath fluid box is securely tightened.
   c. Disconnect and reconnect the sheath and waste lines to the unit. The connections should click when they are inserted, signaling that they are secured. Also make sure the fittings are not cracked.
   d. Make sure the sample tubing is tightly connected above the sample needle, below the blue light.
   e. When the Luminex analyzer is turned on, does the compressor engage? The low humming engine sound at first and then it turns off automatically after the instrument pressurizes. If not, contact Luminex Technical Support.
   f. If the compressor is engaging but pressure is not building within the system, disconnect the sheath and waste lines from the Luminex analyzer. Run a prime and notice whether air pressure builds. If so, air must be leaking from the lines somewhere outside of the Luminex analyzer. Contact Luminex Technical Support.

7. **Acquisition Issues**
   a. Check to make sure the correct bead set is selected.
   b. Pipette the sample up and down to make sure that the microspheres are re-suspended.
   c. Verify that the sample probe height has been adjusted properly.
   d. Try to calibrate the unit, if calibration is not successful, there may be a clog in the system *See Appendix D: Basic Instrument Troubleshooting Step 1: Sample Probe Clog.*
   e. Recalibrate the system. If the calibration fails, call Luminex Technical Support.
8. **Software Freezes**
   a. Archive the Luminex Database, See *Appendix I: Archive*.
   b. Defrag computer.
   c. Check computer hard drive memory availability, if nearing capacity, consider emptying hard drive to external storage.

Appendix E: Re-reading Individual Sample Wells

1. On the **Batches** tab, click **Create a New Batch from an existing Protocol**.
2. Enter a distinguishing **Batch Name** for the samples to be re-run.
3. Select the same protocol that was used for the first reading.
4. Click **Next**.
5. Select the wells to be read, and click for **Unknown**.
6. Manually enter the sample IDs in the **ID** field.
7. Press **Run** – a new output file and run files will be created.

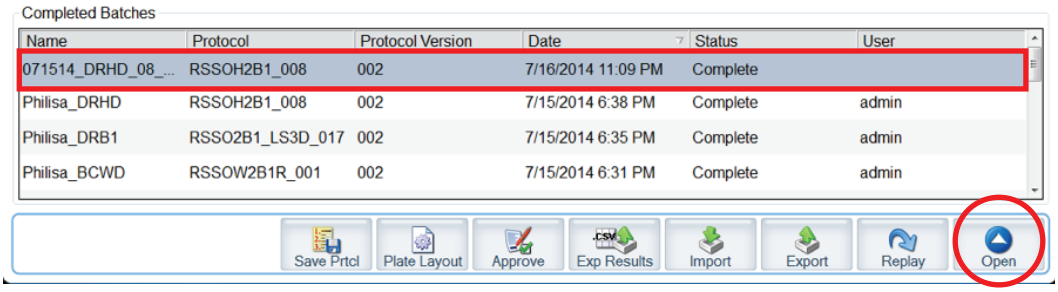
Appendix F: Replaying a Batch

1. On the **Results** tab, select the **Saved Batches** sub-tab.
2. Select the completed batch to replay, and then select the **Replay** button.
3. A prompt will open **Select Replay Mode**, select the **Replay Batch** bubble and then click okay.
4. Re-name the batch, and then select the protocol to use to replay the batch.
5. Click **Next**.
6. On the **Plate Layout** section, select by dragging all the wells to be replayed. Then select for **Unknown**.
7. Next, either click **Import List** to import a Sample ID Import list to the batch, or edit the Sample **ID** of each well by double clicking in the **ID** field next to the corresponding well position, and give each “ID” a sample name.
8. Click the **Replay Batch** – an output file will be created.
   Note: The LABScan3D unit does not need to be ON to replay a batch.

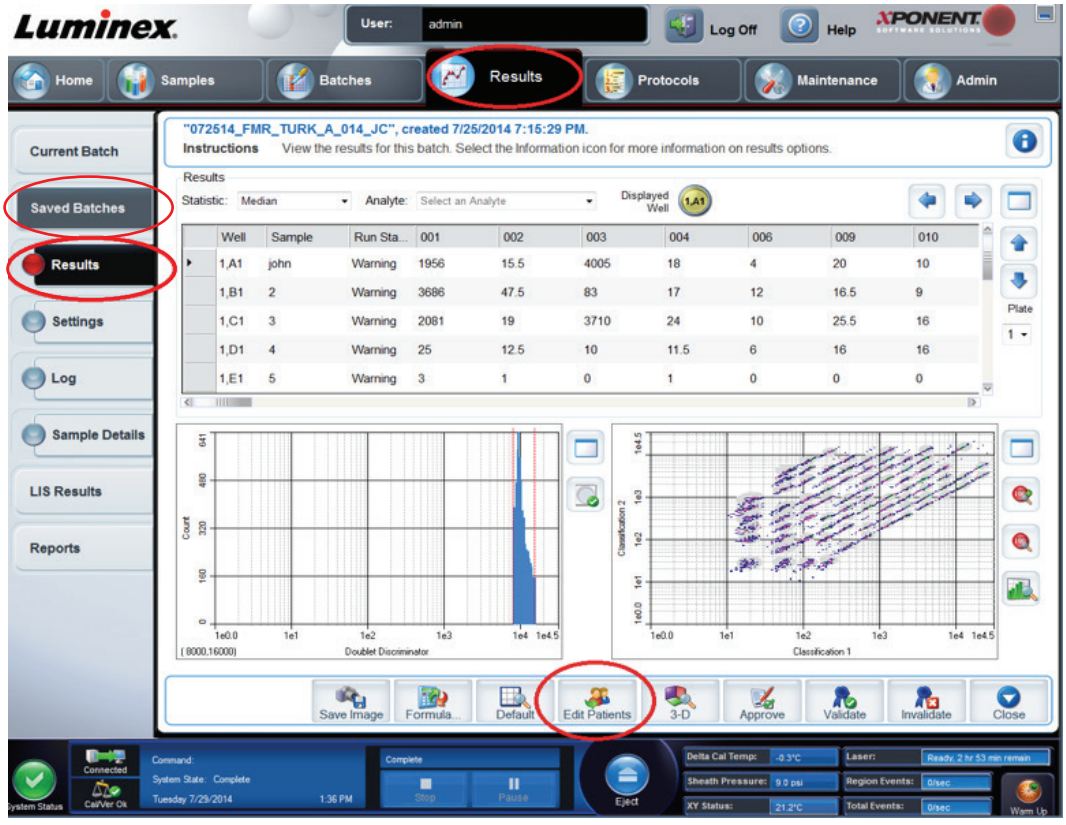
Appendix G: Edit Patient ID/Sample ID

Patient ID/Sample ID maybe changed after a batch has already completed running.

1. Select the **Results** tab> **Saved Batches**.
2. Highlight the batch with the Sample **ID**s that need editing and click **Open**.

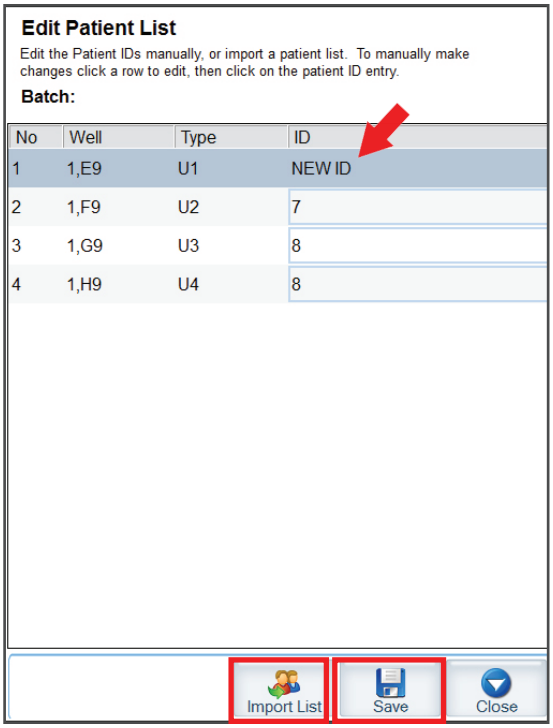


3. Select the **Edit Patients** button at the bottom.

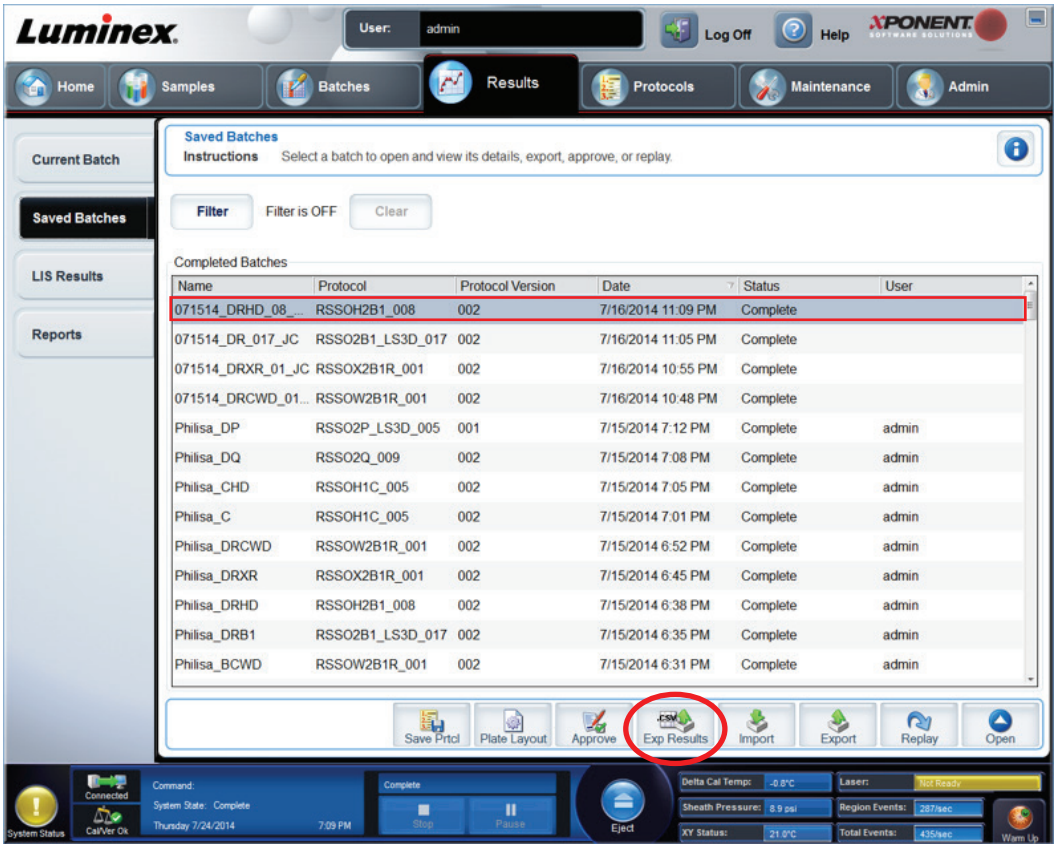


4. An **Edit Patient List** window will open, select the **ID**s to change and edit the **ID** names.
   Note: An entire new **Import List** may be imported by clicking **Import List**.

5. Once all **ID**s have been edited, click **Save**.



6. Re-select the batch and then click the **Exp Results** button.
7. Results will be exported to location indicated in **LABScan3D CSV Options Settings** (see page 9).



Appendix H: Maintaining Fluids

1. Periodically monitor sheath fluid levels. Replace the sheath fluid container as needed as well as the waste fluid container.

   Note: If the LABScan3D instrument operates with an empty sheath fluid container, the lack of sheath fluid may interrupt a sample acquision and prevent further data from being collected.

   CAUTION: Use only xMAP Sheath Fluid or another Luminex-approved sheath fluid. Use of any other sheath fluid constitutes improper use and can void the warranty provided by Luminex and/or its authorized partner.

2. Optimally, the waste line should be routed to a laboratory drain or waste container.
   a. If a waste container is used, monitor waste fluid levels periodically. The volume of the waste container should be at least as large as the volume of the sheath container.
   b. Do not allow the waste fluid container to overflow. Empty the waste fluid container **each time the sheath fluid container is replace or filled**.
   c. Place the waste fluid container at least three feet below the surface on which the LABScan3D instrument rests. Do not place the waste fluid container on top of the instrument. Do not move the waste line vertically while the LABScan3D instrument is running. Contact Luminex Technical Support before relocating the waste fluid container or rerouting the waste line. The line may be moved temporarily for cleaning and maintenance.

3. To replace the sheath fluid container:
   a. Disconnect both the sheath fluid line and the waste fluid line from each of their corresponding containers. (Careful not to touch the sheath fluid line, except for the part that resides outside the sheath fluid container).
   b. Place the sheath fluid line into a new container of sheath fluid.
   c. Move the empty sheath fluid container to become the new waste fluid container or discard the waste from the waste fluid container in accordance with all local, state, federal, and country specific biohazard handling regulations, and replace again for use as the waste container.
   d. The sheath line in should be secured tightly to the sheath container.
   e. Prime the LABScan3D instrument at least 3 times.

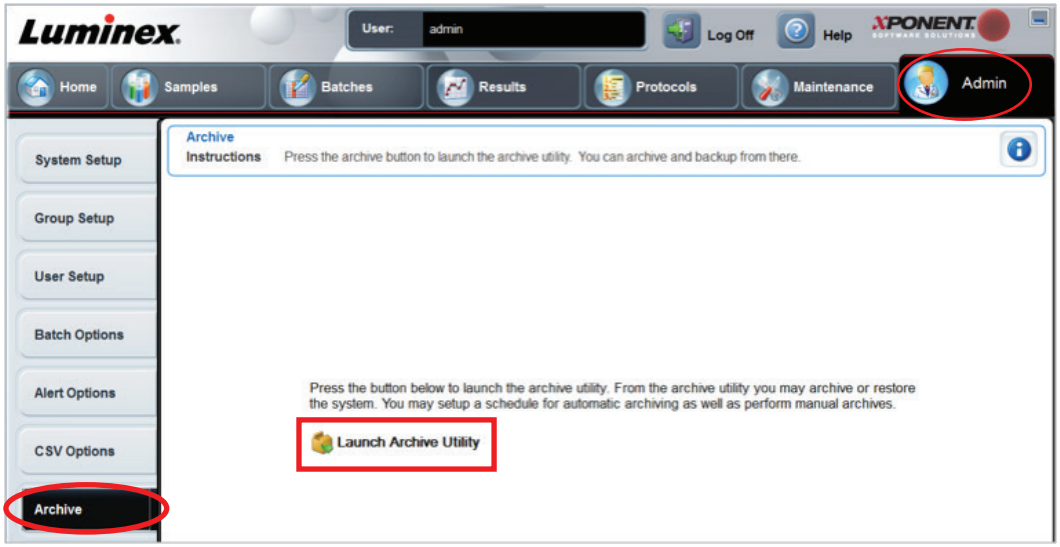
   WARNING: Waste fluid can contain bio-hazardous infectious agents. Follow appropriate biosafety procedures and use personal protective equipment such as gloves, gowns, laboratory coats, face shields (or mask and eye protection), respirators, and ventilation devices.

Appendix I: Archive

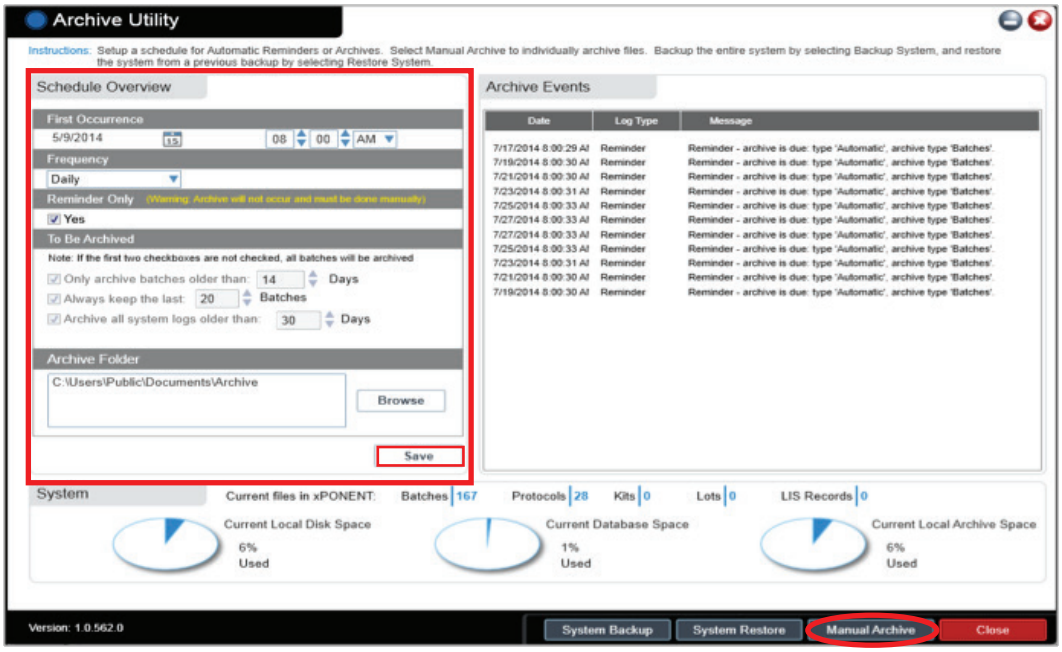
Note: Files will fill up the Luminex SQL database.

Note: Batch output data files are very large, in order to maintain software speed, regular archives should be performed.

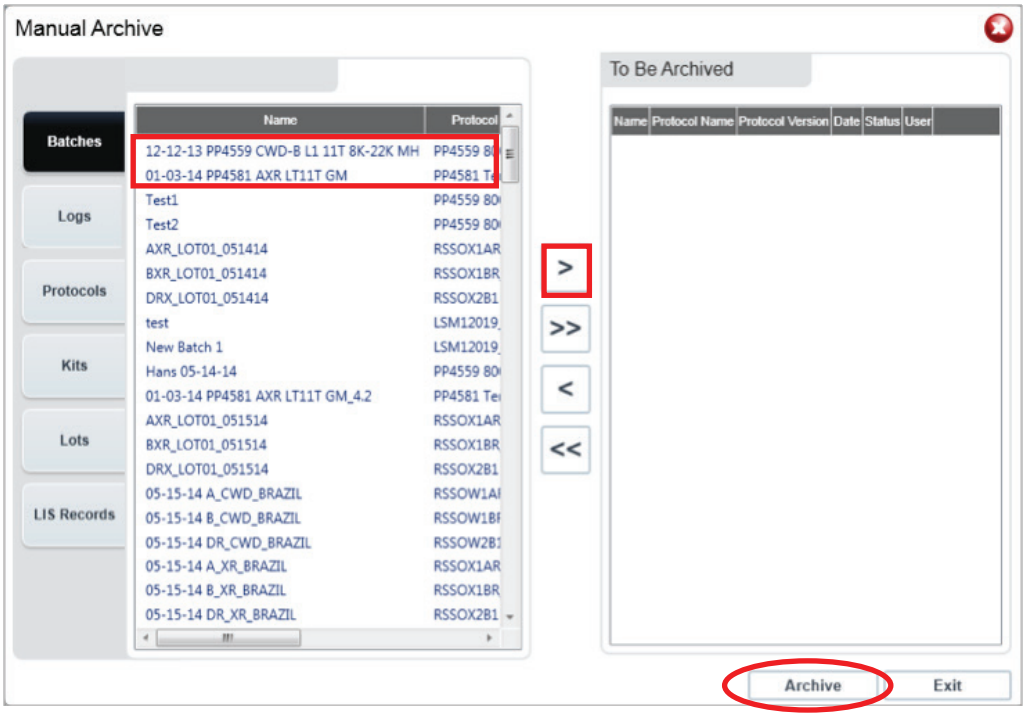
1. The **Archive Utility** will allow the user to schedule archives.
   a. Select the **Admin** tab > **Archive**, then click **Launch Archive Utility**



   b. The **Archive Utility** will open allowing scheduling an archive, be sure to **Save** after making changes to **Schedule Overview**.
   c. Batches may also be manually archived (i.e. large batches that take up a lot of database space).
   d. Select the **Manual Archive** button.

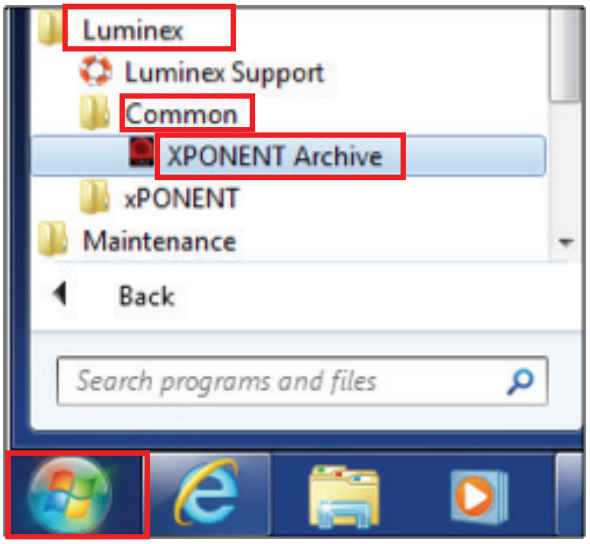


e. Select the Batches to be archived, click the > to add the selected batches and click the **Archive** button (click the **>>** to add all of the batches).



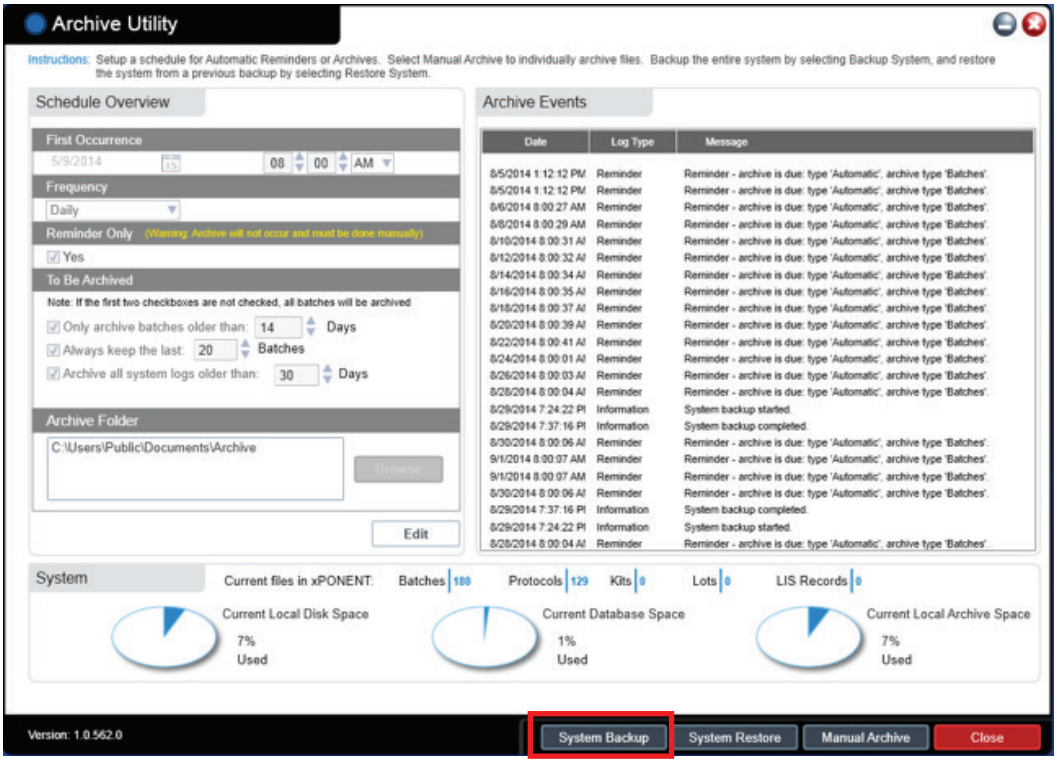
2. The **Archive Utility** also allows the user to backup the entire xPONENT database.
   a. Select the **Windows Start** menu.

   b. Select the following file path **All Programs>Luminex>Common>XPONENT Archive**.



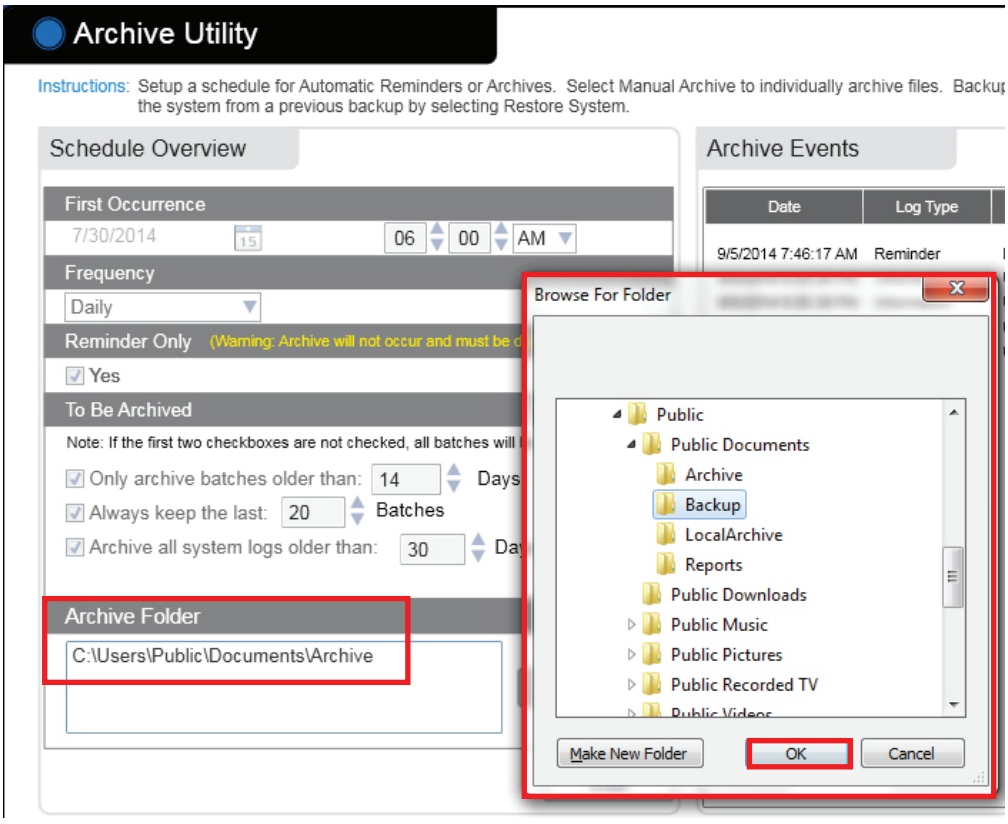
   c. The **Archive Utility** will launch.

d. Select the **System Backup** button from the bottom of the **Archive Utility** window.

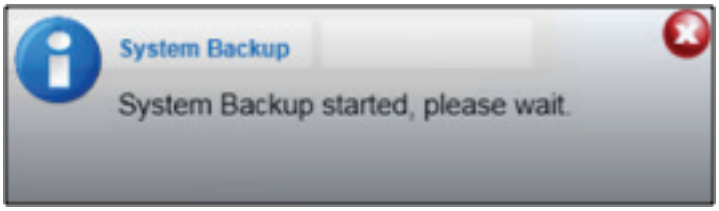


e. A **Browse For Folder** window will open.

f. Browse to a location to backup the system to (Default **C:\Users\Public Documents\Archive**) and click **OK**.



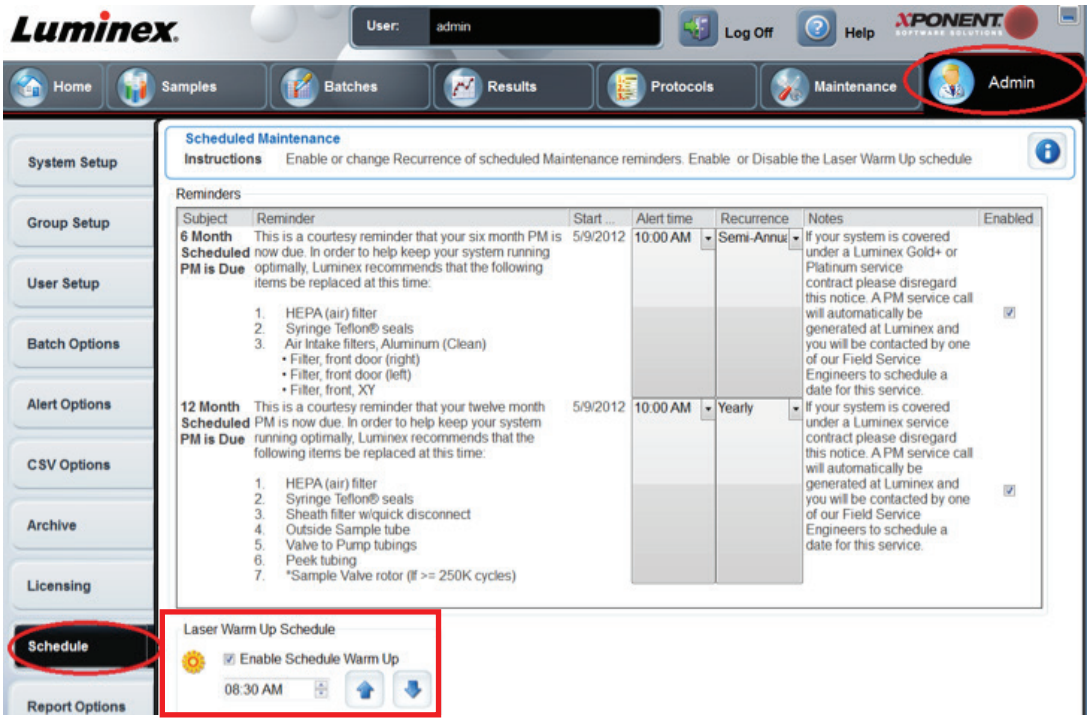
g. The following prompt will appear in the bottom right corner of the screen.



h. Once completed, the following prompt will appear in the bottom right corner of the screen **X** the prompt.

Appendix J: Schedule

1. Select the **Admin** tab > **Schedule**.
   a. The schedule tab displays 6 Month and 12 Month PM due dates


Luminex
User: admin
Log Off
Help
XPONENT
Home
Samples
Batches
Results
Protocols
Maintenance
Admin
System Setup
Group Setup
User Setup
Batch Options
Alert Options
CSV Options
Archive
Licensing
Schedule
Report Options
Scheduled Maintenance
Instructions Enable or change Recurrence of scheduled Maintenance reminders. Enable or Disable the Laser Warm Up schedule
Reminders
Subject Reminder Start ... Alert time Recurrence Notes Enabled
6 Month Scheduled PM is Due This is a courtesy reminder that your six month PM is now due. In order to help keep your system running optimally, Luminex recommends that the following items be replaced at this time:
1. HEPA (air) filter
2. Syringe Teflon® seals
3. Air Intake filters, Aluminum (Clean)
• Filter, front door (right)
• Filter, front door (left)
• Filter, front, XY
5/9/2012 10:00 AM Semi-Annu
If your system is covered under a Luminex Gold+ or Platinum service contract please disregard this notice. A PM service call will automatically be generated at Luminex and you will be contacted by one of our Field Service Engineers to schedule a date for this service.
12 Month Scheduled PM is Due This is a courtesy reminder that your twelve month PM is now due. In order to help keep your system running optimally, Luminex recommends that the following items be replaced at this time:
1. HEPA (air) filter
2. Syringe Teflon® seals
3. Sheath filter w/quick disconnect
4. Outside Sample tube
5. Valve to Pump tubings
6. Peek tubing
7. *Sample Valve rotor (If >= 250K cycles)
5/9/2012 10:00 AM Yearly
If your system is covered under a Luminex service contract please disregard this notice. A PM service call will automatically be generated at Luminex and you will be contacted by one of our Field Service Engineers to schedule a date for this service.
Laser Warm Up Schedule
Enable Schedule Warm Up
08:30 AM

b. Laser warm up may also be schedule from this tab.

Note: Laser warm up is also available from every screen by clicking the **Warm Up** button.

Note: It takes approximately 30 minutes for the lasers to warm-up before being able to Calibrate or Verify the unit.

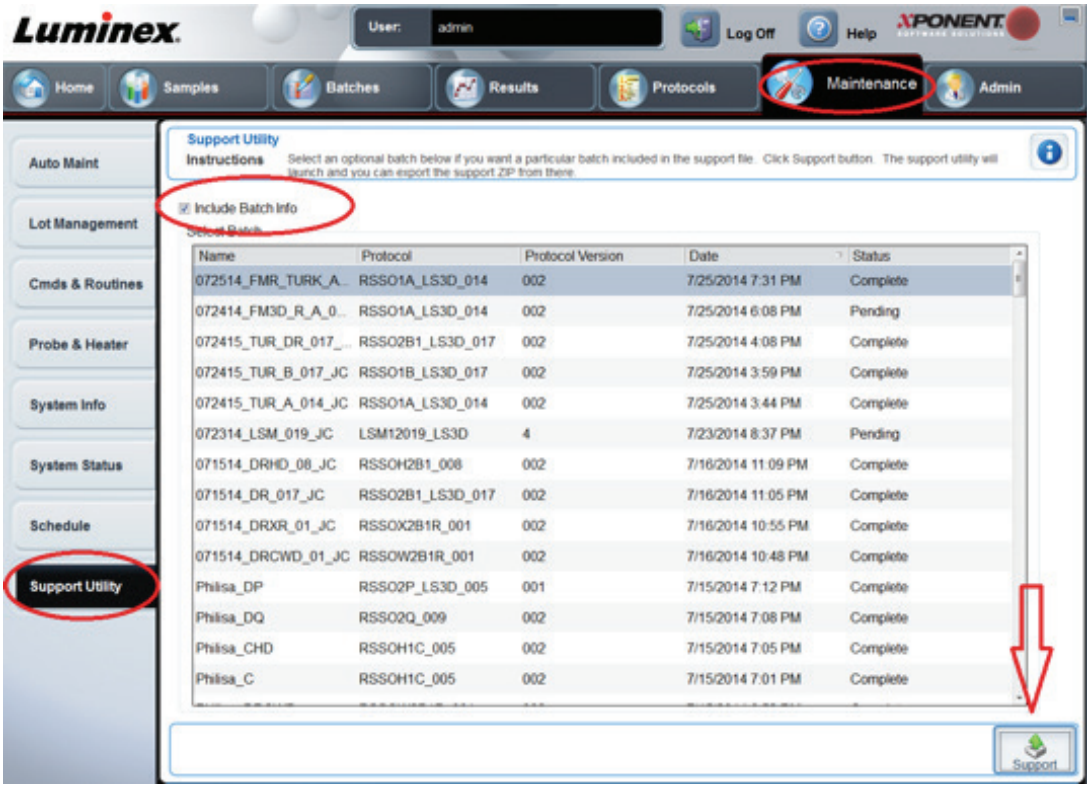
Appendix K: Support Utility

If Luminex technical support requests the **Support Utility Output File**, the **Support Utility** maybe used to generate the **Support Utility Output File**.

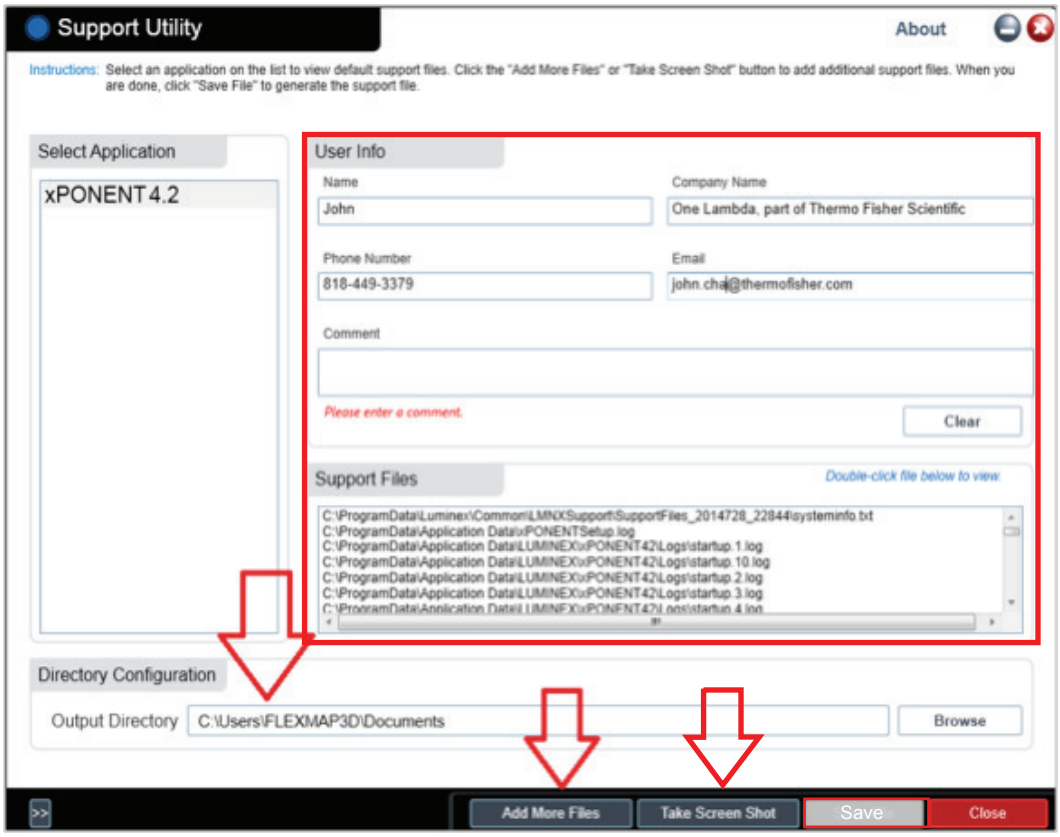
1. Click the **Maintenance** tab > **Support Utility.**

   Note: In order to include Batch info, make sure to tick the **Include Batch Info** check box and select the batch to include below.

2. Click the **Support** button and the **Support Utility** will open in a new window.



3. Fill out the **User Info**, designate the location for the **Support Utility Output File** under **Output Directory**, add any additional files by clicking **Add More Files**, add any screen shots by clicking **Take Screen Shot**, then click **Save File**, the **Support Utility Output File** will be generated in a zip file at the location designated under **Output Directory**.



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For Luminex License Code Information:
Go to **Admin>Licensing**

For Luminex Serial Number:
Go to **Maintenance>System Info**

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